2025

Annual Report

to Shareholders

Theriva Biologics, Inc.

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-K

☒ **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

Commission file number: 001-12584

THERIVA BIOLOGICS, INC.

(Exact name of registrant as specified in its charter)

Nevada *(State or other jurisdiction of incorporation or organization)*	**13-3808303** *(I.R.S. Employer Identification No.)*
9605 Medical Center Drive, Ste. 270 **Rockville, MD** *(Address of principal executive offices)*	**20850** *(Zip Code)*

Registrant's telephone number, including area code:
(301) 417-4364

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	TOVX	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 issuer: (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 (section 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 the definitions 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 Exchange Act).

Yes ☐ No ☒

The aggregate market value of the registrant's common stock held by non-affiliates of the registrant as of June 30, 2025, the last business day of the registrant's recently completed second fiscal quarter, was approximately $3.9 million based on $0.43, the closing price of the registrant's common stock as reported by the NYSE American on that date.

As of March 10, 2026, the registrant had 45,892,668 shares of common stock outstanding.

Documents incorporated by reference: **None**

THERIVA BIOLOGICS, INC.

FORM 10-K
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PART I

Special Note Regarding Forward-Looking Statements

This Annual Report on Form 10-K (this "Annual Report") contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), that involve substantial risks and uncertainties. The forward-looking statements are contained principally in Part I, Item 1. "Business," Part I, Item 1A. "Risk Factors," and Part II, Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations," but are also contained elsewhere in this Annual Report. In some cases you can identify forward-looking statements by terminology such as "may," "should," "potential," "continue," "expects," "anticipates," "intends," "plans," "believes," "estimates," and similar expressions. These statements are based on our current beliefs, expectations, and assumptions and are subject to a number of risks and uncertainties, many of which are difficult to predict and generally beyond our control, that could cause actual results to differ materially from those expressed, projected or implied in or by the forward-looking statements.

You should refer to Item 1A. "Risk Factors" section of this Annual Report for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this Annual Report will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. We do not undertake any obligation to update any forward-looking statements.

Unless the context requires otherwise, references to "we," "us," "our," "Theriva," and "Theriva Biologics," refer to Theriva Biologics, Inc. and its subsidiaries.

On October 26, 2024, we effected a one for twenty-five reverse stock split (the "Reverse Stock Split") of our authorized, issued and outstanding common stock, par value $0.001 per share ("Common Stock"). Unless otherwise noted, all references to share amounts from dates prior to completion of the Reverse Stock Split that are included in this Annual Report have been retroactively restated to reflect the Reverse Stock Split.

Summary Risk Factors

The following is a summary of the key risks relating to the Company. A more detailed description of each of the risks can be found below under Item 1A. Risk Factors.

Risks Related to Our Financial Position and Capital Requirements

- Our consolidated financial statements as of December 31, 2025 have been prepared assuming that we will continue as a going concern for the next twelve months.
- We will need to raise additional capital for our planned clinical trials.
- We expect to continue to incur significant operating and capital expenditures and we will need additional funds.
- The actual amount of funds we will need to operate is subject to many risk factors, some of which are beyond our control.
- We currently have a limited operating history as an oncology company, no products approved for commercial sale, have no significant source of revenue and may never generate significant revenue.
- We cannot provide assurances that additional material weaknesses will not occur in the future.
- We expect to seek to raise additional capital in the future, which may be dilutive to stockholders.
- Our operating results may fluctuate significantly, which makes our future operating results difficult to predict.
- If our acquired intangible assets become impaired, we may be required to record a significant charge to earnings.
- A prolonged U.S. federal government shutdown could materially and adversely affect our business and operations.
- Federal budget and debt - ceiling disputes may adversely affect capital markets and our financing activities.

Risks Related to Our Business

- Prior to 2022 we did not conduct any research and development activities directed to cancer diagnosis, treatment or prevention and there can be no assurance that we will successfully be able to do so.
- The development and commercialization of oncolytic viruses have experienced certain challenges.
- Our research and development efforts may not succeed in developing successful products and technologies.
- We may not realize the benefits from any strategic alliances we form or licensing arrangements we enter into.
- We may not be able to retain rights we license or relationships needed to develop, manufacture, and market our products.

- We may incur additional expenses in connection with our licenses, collaboration arrangements and development efforts.
- Developments by competitors may render our products or technologies obsolete or non-competitive.
- We may seek to selectively establish collaborations, and, if we are unable to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans.
- If the parties we depend on for product manufacturing are unsuccessful in providing adequate drug supply, or if existing drug supply becomes unusable, it may delay or impair our ability to develop, manufacture and market our product candidates.
- Any problems obtaining the drugs that we administer in combination with VCN-01, could result in a trial delay or interruption.
- We may fail to retain or recruit necessary personnel, and we may be unable to secure the services of consultants.
- Inadequate funding for certain government agencies could negatively impact our business and timelines.
- Global health crises or other disruptions to global trade and supply lines may adversely affect our planned operations.
- Business disruptions could seriously harm our future revenue and financial condition and increase costs and expenses.
- Unfavorable economic conditions could adversely affect our business, financial condition or results of operations.
- We rely extensively on our information technology systems which are vulnerable to risks.
- Our business and operations would suffer in the event of computer system failures.
- Failure to maintain the security of information relating to our patients, customers, employees and suppliers could expose us to litigation, government enforcement actions and costly response measures and harm our reputation.
- We may face particular data protection, data security and privacy risks in connection with data protection regulations.

Regulatory Risks

- If we do not obtain the necessary regulatory approvals we may not be able to develop or sell our product candidates.
- Clinical trials are very expensive, time consuming, and difficult to design and implement.
- The results of our clinical trials may not support our proposed product candidate claims and the results of preclinical studies and completed clinical trials are not necessarily predictive of future results.
- Difficulties in enrolling, retaining, or completing patients in our clinical trials or delays in enrollment are expected to result in our clinical development activities being delayed or otherwise adversely affected.
- Patients who are administered our product candidates may experience unexpected side effects or other safety risks that could cause a halt in clinical development, preclude approval or limit the commercial potential of the product candidate.
- It is possible that we may not be able to obtain or maintain orphan drug designation or exclusivity for our drug candidates.
- Fast Track designation by the FDA does not assure FDA approval.
- We may not be eligible to receive a priority review voucher despite rare pediatric disease designation for VCN-01
- Our product candidates, if approved for sale, may not gain acceptance among physicians, patients and the medical community.
- We depend on third parties, including researchers and sublicensees, who are not under our control.
- We currently have no marketing, sales or distribution organization and have no experience in marketing products as a company.
- Reimbursement may not be available for our product candidates, which would impede sales.
- Healthcare reform measures could hinder or prevent our product candidates' commercial success.
- If we fail to comply with state and federal healthcare regulatory laws, we could face substantial penalties, damages, fines, disgorgement, exclusion from participation in governmental healthcare programs, and the curtailment of operations, any of which could harm our business.
- If we obtain approval to commercialize our clinical product candidates outside of the United States, a variety of risks associated with international operations could harm our business
- If product liability lawsuits are successfully brought against us, we may incur substantial liabilities.
- We and our subsidiaries are subject to U.S. and foreign tax laws, and changes to such tax laws or differing interpretation of those laws by the relevant governmental authorities could adversely affect our business and operating results.

Intellectual Property Risks

- We rely on patent applications and various regulatory exclusivities to protect some of our product candidates and our ability to compete may be limited or eliminated if we are not able to protect our products.
- We may incur substantial costs as a result of litigation or proceedings relating to protecting our intellectual property rights.
- If we infringe the rights of others, we could be prevented from selling products or forced to pay damages.
- We enjoy restricted geographical protection with respect to certain patents.
- We may become subject to claims challenging inventorship, ownership or validity of our intellectual property

Risks Related to Our Securities

- We cannot assure you that our Common Stock will be liquid or that it will remain listed on the NYSE American exchange.
- We expect to seek to raise additional capital in the future, which may be dilutive to stockholders.
- The market price of our Common Stock has been and may continue to be volatile and adversely affected by various factors.

- Our Articles of Incorporation and bylaws and Nevada law have anti-takeover effects that could discourage, delay or prevent a change in control, which may cause our stock price to decline.
- We do not intend to pay dividends in the foreseeable future on our Common Stock.
- Resales of our stock in the public market by our stockholders may cause the market price of our stock to fall.
- The shares of Common Stock offered under our current Amended and Restated At The Market Issuance Sales Agreement may be sold in "at the market" offerings, and investors who buy shares at different times will likely pay different prices.

Item 1. ***Business.***

Overview

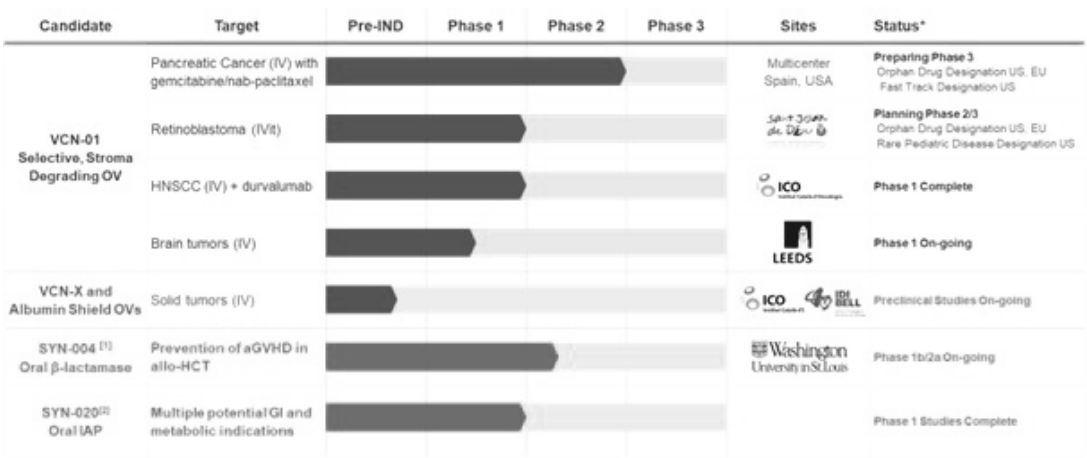
We are a diversified clinical-stage company developing therapeutics designed to treat cancer and related diseases in areas of high unmet need. As a result of the Company's acquisition of Theriva Biologics, S.L. ("VCN", formerly named VCN Biosciences, S.L.), in March 2022, as described in more detail below (the "Acquisition"), we transitioned our strategic focus to oncology through the development of VCN's new oncolytic adenovirus platform designed for intravenous and intravitreal delivery to trigger tumor cell death, to improve access of co-administered cancer therapies to the tumor, and to promote a robust and sustained anti-tumor response by the patient's immune system. Our lead product candidate, VCN - 01 (zabilugene almadenorepvec), is a clinical stage oncolytic human adenovirus that is modified for tumor - selective replication and to express an enzyme, PH20 hyaluronidase. VCN - 01 has been evaluated in a Phase 2b clinical study for the treatment of pancreatic cancer ("VIRAGE"), and a Phase 1 clinical study for the treatment of retinoblastoma, as well as various other Phase 1 clinical studies for the treatment of other solid tumors including head and neck squamous cell carcinoma.

Prior to the Acquisition, our focus was on developing therapeutics designed to treat gastrointestinal (GI) diseases which included our clinical development candidates: (1) SYN-004 (ribaxamase), which is designed to degrade certain commonly used intravenous (IV) beta-lactam antibiotics within the GI tract to prevent microbiome damage, thereby preventing overgrowth and infection by pathogenic organisms such as *Clostridioides difficile* infection (CDI) and vancomycin resistant Enterococci (VRE), and reducing the incidence and severity of acute graft-versus-host-disease (aGVHD) in allogeneic hematopoietic cell transplant (HCT) recipients, and (2) SYN-020, a recombinant oral formulation of the enzyme intestinal alkaline phosphatase (IAP) produced under current good manufacturing practices ("cGMP") conditions and intended to treat both local GI and systemic diseases.

In February 2026, we entered into a license agreement (the "Rasayana License Agreement") with Rasayana Therapeutics, Inc. ("Rasayana"), pursuant to which we granted Rasayana an exclusive worldwide license with the right to grant sublicenses to research, develop, manufacture and commercialize any Product (as such term is defined in the Rasayana License Agreement), which includes SYN-020, comprising, containing, or covered by the Licensed IP (as such term is defined in the Rasayana License Agreement) and/or devised, developed, or produced using the Licensed IP. Pursuant to the terms of the Rasayana License Agreement, Rasayana will assume all responsibility and costs for the development and commercialization of the Products. We believe that this arrangement will provide us with potential to derive value from our SYN-020 asset, without the need for us to continue to invest additional working capital into the further development of the product candidate, thereby allowing us to focus our efforts and expenditures on the development of our oncology assets.

Additionally, as part of our strategic transformation into an oncology focused company, we are exploring value creation options for our SYN-004 asset, including out-licensing or partnering.

Our Current Product Pipeline



Based on management's current beliefs and expectations

allo-HCT allogeneic hematopoietic cell transplant. **HNSCC** head and neck squamous cell carcinoma. **IV** intravenous. **IVit** intravitreal. For other abbreviations see the text.

[1]Final Phase 1b/2a study cohort contingent on grant funding or partnership.

[2]Pursuant to the Rasayana License Agreement, commencing February 7, 2026, Rasayana is responsible for all development and commercialization efforts, including all costs related thereto, of SYN-020, and is obligated to use commercially reasonable efforts to meet certain specified development milestones, as more particularly set forth in the Rasayana License Agreement.

Additional products with preclinical proof-of-concept include SYN-006 (carbapenemase) to prevent aGVHD, CDI, and microbiome damage in patients treated with carbapenem antibiotics and SYN-007 (ribaxamase) DR to prevent antibiotic associated diarrhea with oral β-lactam antibiotics.

Our Current Oncology-Focused Pipeline

Oncolytic Viruses

Our oncology platform is based on oncolytic virotherapy ("OV therapy"), which exploits the ability of certain viruses to kill tumor cells and trigger an anti-tumor immune response. This novel class of anticancer agents has unique mechanisms of action compared to other cancer drugs. Oncolytic viruses ("OVs") exploit the fact that cancer cells contain mutations that cause them to lose growth control and form tumors. Once inside a tumor cell, OVs exploit the tumor cell machinery to generate thousands of additional copies of the virus, which then kill the tumor cell and spread to neighboring cells, causing a chain reaction of cell killing. This infection and tumor cell killing by OVs also alerts the immune system, which can then attack the virus infected tumor cells to help destroy the tumor in some instances.

Our OV product candidates are engineered to efficiently infect and selectively replicate to a high extent in tumor cells versus normal host cells, which enables intravenous delivery. By contrast, many other OVs in clinical development today are administered by direct injection into the tumor. Intravenous delivery has the potential to expand the therapeutic effect of OVs because the virus can infect both the primary tumor and tumor metastases throughout the body.

Our lead product candidate VCN-01 (zabilugene almadenorepvec), is a clinical stage oncolytic human adenovirus that is modified to express an enzyme, PH20 hyaluronidase, that is designed to degrade hyaluronan in the tumor stroma, which helps the virus and other

molecules to penetrate and spread throughout the tumor. VCN-01 can be used alone or in combination with other cancer therapies, such as chemotherapy and immunotherapy, for difficult to treat cancers. An expanding intellectual property portfolio supports our oncology programs, and because our products are characterized as biologics with Orphan Drug designation in our target indications, if approved by the FDA they will be further protected by data and/or market exclusivity.

VCN-01 (zabilugene almadenorepvec) — An oncolytic human type-5 adenovirus engineered for intravenous administration and to express a tumor matrix degrading enzyme (PH20 hyaluronidase) the goal of which is to facilitate the entry of therapeutics and immune cells into tumors

VCN-01 is a genetically modified oncolytic adenovirus that has been engineered to contain four independent genetic modifications on the backbone of the wild-type human adenovirus serotype 5 (HAd5) genome. These modifications have been shown in preclinical and clinical studies to confer tumor selective replication and antitumor activity. VCN-01 was engineered to replicate in and kill virtually all types of solid tumor cells, to expose tumor neoantigens of lysed tumors, to reduce liver tropism, and to express PH20 hyaluronidase to enhance the penetration of virus, chemotherapy, immuno-oncology therapy, and immune cells into the tumor.

Malignant tumors are made up of tumor cells as well as significant supporting tissue known as tumor stroma. The tumor stroma supports the formation and growth of tumors and contains cells and other components that are required for robust tumor growth and metastasis. The stroma also forms an effective barrier to the entry of therapeutic agents such as chemotherapy and immuno-oncology products. A key structural component of the tumor stroma is hyaluronic acid, and tumor levels of hyaluronic acid have been clinically associated with reduced survival in metastatic pancreatic cancer patients. VCN-01 is designed to overcome the stroma barrier problem by expressing the hyaluronan degrading enzyme PH20 hyaluronidase after it infects tumor cells. Expression of PH20 by VCN-01 is designed to degrade the hyaluronic acid within the tumor stroma and to improve virus spread throughout the tumor. Based upon the foregoing, we believe our OV platform, exemplified by VCN-01, represents a new and potentially powerful form of therapy to be combined with tumor cell killing, anti-tumor immunity and stroma destruction after intravenous delivery.

The VCN-01 product candidate is provided as a sterile liquid concentrate that is diluted for infusion or injection. The proposed therapeutic indication for VCN-01 is the treatment of solid tumors, as its selectivity mechanism relies on cellular properties shared by virtually all human tumor cells. Our initial indication for clinical development is unresectable metastatic pancreatic cancer, a disease for which there is currently no cure and only limited therapeutic options.

At the time of the filing of this Annual Report, VCN-01 has been administered to 142 patients across multiple Phase 1 clinical trials and the Phase 2 VIRAGE trial, including patients with pancreatic cancer, head and neck squamous cell carcinoma, ovarian cancer, colorectal cancer, and retinoblastoma.

Pancreatic Ductal Adenocarcinoma

Cancer of the pancreas consists of two main histological types: cancer that arises from the ductal (exocrine) cells of the pancreas or, much less often, cancers that may arise from the endocrine compartment of the pancreas. Pancreatic ductal adenocarcinoma (“PDAC”) accounts for more than 90% of all pancreatic tumors. It can be located either in the head of the pancreas or in the body-tail. Pancreatic cancer usually metastasizes to the liver and peritoneum. Other less common metastatic sites are the lungs, brain, kidney and bone. In its early stages, pancreatic cancer does not typically result in any characteristic symptoms. In many instances, progressive abdominal pain is the first symptom. Therefore, in most cases, pancreatic cancer is diagnosed in its late stages (locally advanced non-metastatic or metastatic stage of the disease) when surgical resection and possibly curative treatment is not possible. It is generally assumed that only 10% of cases are resectable at presentation, whereas 30-40% of patients are diagnosed at the locally advanced/unresectable stage and 50-60% present with distant metastases.

PDAC Clinical Unmet Need and Market Opportunity

PDAC is currently the 3rd leading cause of cancer-related deaths in the United States and the 4th leading cause of cancer-related deaths in the European Union and it is projected to become the second leading cause of cancer-related deaths in the United States before 2030. Despite significant research efforts, minimal progress has been achieved to date. The five-year overall survival rate is < 10% and has not substantially improved over the last 30 years. Surgery is the only treatment that offers the prospect of long term-survival; however, the 5-year survival rate for the limited number of patients in whom resection is possible remains low (20 – 30 %). Patients with advanced disease are often managed with chemotherapy. In recent years, the combination of gemcitabine with albumin-bound paclitaxel (GA), and the combination of folic acid, 5-fluorouracil, irinotecan and oxaliplatin (FOLFIRINOX) have emerged as the standard of care. In 2024, liposomal irinotecan (ONIVYDE®), which was previously approved for second line PDAC in combination with fluorouracil and

leucovorin, was approved in the United States and Europe as first line therapy for metastatic PDAC when administered along with oxaliplatin 5-FU and leucovorin (the NALIRIFOX regimen). However, the results are still very poor and new therapeutic interventions are needed. In recent years, the prevalence of PDAC has increased, which increase has been particularly evident in younger people. The rising incidence of pancreatic cancer and its current economic burden place increased pressure to improve outcomes for patients.

In May 2011, the Committee for Orphan Medicinal Products ("COMP") from the European Medicines Agency ("EMA") recommended granting Orphan Medicinal Product Designation to VCN-01 for the treatment of pancreatic cancer and in June 2011, the European Commission ("EC") confirmed the designation under Regulation No 141/2000 of the European Parliament and of the Council.

In June 2023, the FDA granted Orphan Drug designation to VCN-01 for the treatment of pancreatic cancer.

In May 2024, the FDA granted Fast Track designation to VCN-01 for the treatment of pancreatic cancer.

Phase 1a/Proof of Concept Trial of VCN-01 (zabilugene almadenorepvec) by intratumoral administration in PDAC

In September 2019, VCN presented a poster at the European Society for Medical Oncology ("ESMO") annual meeting describing initial mechanism of action data from a multicenter, Phase 1 dose escalation study of intratumoral ("IT") VCN-01 administered to pancreatic cancer patients in combination with standard doses/schedules of either gemcitabine or nab-paclitaxel plus gemcitabine (NCT02045589). The study was conducted at three hospitals in Spain and 8 patients with confirmed histologic diagnosis of unresectable PDAC amenable to endoscopic ultrasound guided ("EUS") injection were treated with 3 injections (coinciding with 1st day of the chemotherapy cycles) at two different dose levels of VCN-01 (6 patients had metastatic disease and 2 had locally advanced disease). The treatment regimen was generally well-tolerated. VCN-01-related adverse events were dose-dependent and mainly consisted of asthenia (6 patients), fever (4 patients), and transaminase increases (3 patients). One patient died from severe intra-abdominal fluid collection that was considered to be related to VCN-01 treatment. Evaluation of virus pharmacokinetics and PH20 levels in serum were consistent with strong virus replication in the tumors. This was supported by the presence of viral particles in tumor cells as assessed in paired tumor biopsies collected before and after treatment. Tumor stiffness was reduced in all VCN-01-injected lesions as measured by elastography. Disease stabilization of injected lesions was observed in 5 out of 6 patients although subsequent tumor progression was observed in most of the patients due to the appearance of new lesions or growth of distant, non-injected, metastatic lesions. This study provided encouraging mechanism of action data for VCN-01; however, intratumoral injection did not appear to deliver sufficiently high VCN-01 levels for effective delivery to non-injected tumors. We believe these results supported the evaluation of the safety/tolerability and potential efficacy of VCN-01 via intravenous administration in combination with chemotherapy and/or immunotherapies for the treatment of advanced PDAC. The results of this study were published in the Journal for Immunotherapy of Cancer. 2021 Nov;9(11):e003254. doi: 10.1136/jitc-2021-003254.

Phase 1 Trial of intravenous VCN-01 (zabilugene almadenorepvec) with or without nab-paclitaxel plus gemcitabine in patients with solid tumors and PDAC

In March 2022, we announced the peer-reviewed publication of data from a Phase 1, multicenter, open-label, dose-escalation study investigating the safety, tolerability and biodistribution of intravenous VCN-01 oncolytic adenovirus with or without standard-of-care (SoC) chemotherapy (gemcitabine/nab-paclitaxel) in patients with advanced solid tumors (NCT02045602). The data, published in the Journal for ImmunoTherapy of Cancer, suggests that intravenous treatment with VCN-01 is feasible and has been well tolerated, with encouraging biological and clinical activity. (Journal for Immunotherapy of Cancer 2022;10:e003255. doi:10.1136/jitc-2021-003255).

Data from the publication had previously been presented, in part, in a poster at the ESMO 2019 annual meeting. The published study was a multicenter, open-label, dose-escalation phase I clinical trial of a single dose of intravenous VCN-01 alone (Part I, 16 patients with advanced refractory solid tumors) or in combination with nab-paclitaxel plus gemcitabine (Part II and III; patients with pancreatic adenocarcinoma). In Part II, 12 patients received VCN-01 dose concurrent with chemotherapy on day 1, whereas in Part III 14 additional patients received the dose of VCN-01 seven days before chemotherapy. The recommended Phase 2 doses (RP2D) were determined to be $1x10^{13}$ viral particles (vp)/patient in Part I, $3.3x10^{12}$ vp/patient in Part II and $1x10^{13}$ vp/patient in Part III. Based on its apparent safety profile and the absence of dose-limiting toxicities, $1x10^{13}$ vp/patient using sequential dosing schedule was selected for further clinical development.

Pharmacokinetic data showed dose linearity, as well as relevant VCN-01 exposure. Analysis of VCN-01 clearance in patients enrolled in Part II did not show significant differences with respect to patients receiving VCN-01 as a single agent. VCN-01 viral genomes were detected in tumor tissue in 5 out of 6 biopsies. A second viral peak in plasma and increased hyaluronidase serum levels suggested replication after intravenous injection in all patients. Increased levels of immune biomarkers (IFNγ, sLAG3, IL-6, IL-10) were found

after VCN-01 administration. In patients with pancreatic adenocarcinoma, the overall response rate (ORR) was 50% for Part II and 50% for Part III, as assessed by the investigators. Median progression free survival (PFS) for patients in Part III was 6.7 months, and median overall survival (OS) was 13.5 months. Eight patients (66.7%) survived more than 12 months. In addition, in April 2021, a subgroup analysis of patients at the RP2D ($1.x10^{13}$ vp/patient followed by nab-paclitaxel plus gemcitabine one week later, n=6) was conducted and showed an ORR of 83%, with a median PFS of 6.3 months and median OS of 20.8 months. Some VCN-01 treated patients appeared to benefit from late-onset responses. This form of delayed anti-tumor activity is not common with chemotherapy but is frequently observed with immunotherapies. We believe an immune mechanism of action associated with the oncolytic activity of VCN-01 may be the underlying explanation. VCN-01 appeared to convert the typically immunosuppressive tumor microenvironment of pancreatic adenocarcinomas into an enhanced inflammatory microenvironment (IDO, CD28, PD-1, CTL signature up-regulation, and collagen formation) after treatment.

Phase 2 Trial of intravenous VCN-01 (zabilugene almadenorepvec) with nab-paclitaxel plus gemcitabine in patients with PDAC

In January 2023, we dosed the first patients in VIRAGE, the Phase 2b randomized, open-label, multicenter clinical trial of systemically administered VCN-01 in combination with SoC chemotherapy (gemcitabine/nab-paclitaxel) as a first line therapy for patients with newly-diagnosed metastatic pancreatic ductal adenocarcinoma. The study was conducted at approximately 17 sites in the US and EU. Two doses of VCN-01 were included in the treatment arm: the 1st dose was administered on day 1, then one week later 3 cycles of gemcitabine and nab-paclitaxel as standard of care was administered. The second VCN-01 dose was administered 7 days before the 4th cycle of chemotherapy (approximately 90 days after the first VCN-01 dose), followed by additional cycles of gemcitabine/nab-paclitaxel chemotherapy.

Patient dosing was initiated in the U.S. in July 2023 and, on September 23, 2024, we announced that we achieved our target patient enrollment of 92 evaluable patients in the VIRAGE Phase 2b clinical trial. Thirty - six patients received their second doses of intravenous VCN-01, which were well tolerated and demonstrated the expected VCN-01 adverse event profile. Positive topline data for the VIRAGE Phase 2b clinical trial from the first-line treatment of 96 newly-diagnosed metastatic PDAC patients was announced in the second quarter of 2025 and is described below.

On January 30, 2024, the accumulated clinical data from patients enrolled across 6 sites open in the U.S. and 9 sites open in Spain were reviewed by an Independent Data Monitoring Committee (IDMC). According to the IDMC's assessment, the ongoing Phase 2b trial continued without any changes to the protocol. No safety concerns were raised based on the evaluation of data presented at the IDMC meeting. Intravenous VCN-01 has been well tolerated and demonstrated a safety profile consistent with prior clinical trials. Importantly, no additional toxicities were observed in patients receiving a second dose of VCN-01, providing the first clinical evidence of the feasibility of repeated systemic dosing.

On May 10, 2024, we presented data demonstrating enhanced anti-tumor effects in human pancreatic cancer xenograft-bearing mice treated with lead product candidate VCN-01 and liposomal irinotecan. These data support the potential synergy of VCN-01 and first-line pancreatic cancer chemotherapy regimens.

On May 23, 2024, we announced that the FDA granted Fast Track Designation (FTD) to lead clinical candidate VCN-01 in combination with gemcitabine and nab-paclitaxel to improve progression-free survival and overall survival in patients with metastatic pancreatic adenocarcinoma.

On December 5, 2024, we announced the outcomes of a Type D meeting with the FDA to obtain guidance on the design of a potential Phase 3 clinical study of VCN-01 in combination with SoC chemotherapy for the treatment of metastatic PDAC ("mPDAC"). The FDA advised that the optimal path forward for the VCN-01 PDAC program is to conduct a stand-alone Phase 3 study of VCN-01 with gemcitabine/nab-paclitaxel. The FDA provided general agreement with our proposed design for a Phase 3 clinical study and indicated that inclusion of additional SoC chemotherapy for mPDAC was not necessary as it would complicate the study design and analysis. The FDA meeting also highlighted the FDA's preferences regarding certain statistical elements of confirmatory clinical studies, including methods for sample size estimation and the study population(s) used for data analysis.

On February 4, 2025, we received Scientific Advice from the Committee for Medicinal Products for Human Use ("CHMP") of the European Medicines Agency ("EMA") on the design of a potential Phase 3 clinical study of VCN-01 in combination with SoC chemotherapy for the treatment of mPDAC. Consistent with feedback from the FDA, CHMP advised that a marketing authorization application ("MAA") for VCN-01 in mPDAC could be supported by positive results from a randomized, controlled, stand-alone Phase 3 study comparing VCN-01 combined with gemcitabine/nab-paclitaxel to gemcitabine/nab-paclitaxel SoC alone. The Scientific Advice also included CHMP suggestions regarding the study populations, inclusion/exclusion criteria, randomization and blinding, priority

endpoints, and proposed statistical strategies for data analysis. An additional comment from the EMA Committee for Orphan Medicinal Products ("COMP") noted that the potential benefit of VCN-01 with gemcitabine/nab-paclitaxel in a Phase 3 trial will be compared with the therapeutic effects of the other approved SoC chemotherapies (FOLFIRINOX, NALIRIFOX) when considering maintenance of the Orphan Medicinal Product status of VCN-01 at the time of an MAA.

On March 31, 2025, we announced that a second Independent Data Monitoring Committee ("IDMC") review of data from the VIRAGE Phase 2b clinical trial in newly-diagnosed mPDAC found that VCN-01 was well tolerated in combination with SoC chemotherapy (gemcitabine/nab-paclitaxel) and the adverse event ("AE") profile was as expected for the patient population and the medications being studied. The VCN-01 AE profile was consistent with that observed in prior clinical trials. The most common VCN-01 related AEs (pyrexia, flu-like illness, vomiting, nausea, and elevated transaminases) were transient and reversible. These AEs were observed to be less frequent and of reduced CTCAE grade after the second VCN-01 dose (administered on day 92) compared to the first VCN-01 dose (administered on day 1). The IDMC noted that the overall type and number of AEs in the VCN-01 treatment group was as expected for the pancreatic cancer population, the duration of treatment, and the administration of an oncolytic virus.

On May 7, 2025, we announced positive topline outcomes from the VIRAGE Phase 2b clinical trial evaluating our lead product candidate VCN-01 (zabilugene almadenorepvec) plus SoC chemotherapy gemcitabine/nab-paclitaxel as a first line therapy for patients with mPDAC for whom gemcitabine/nab-paclitaxel is the recommended first-line treatment option. Topline outcomes for the analysis of the VIRAGE trial includes the following data for first-line treatment of the 96 newly-diagnosed metastatic PDAC patients dosed in the clinical trial:

- In the primary endpoint analysis, the 48 patients treated with at least one dose of gemcitabine/nab-paclitaxel SoC had a median OS) of 8.6 months, while the 48 patients treated with VCN-01 followed by at least one dose of gemcitabine/nab-paclitaxel SoC had a median OS of 10.8 months [Hazard Ratio (HR) = 0.57, 95% CI 0.34-0.96, p=0.0546].

- The improvements in OS in the VCN-01+SoC treatment arm compared to the SoC control arm were reflected in increased progression free survival (PFS) [median PFS 7.0 vs 4.6 months; HR = 0.55, 95% CI 0.34-0.88, p= 0.0105].

- The median duration of response ("DoR") was 5.4 months (n=15) in the SoC control arm, while the median DoR in the VCN-01+SoC treatment arm was doubled to 11.2 months (n=19, HR = 0.22, 95% CI 0.08-0.62, p=0.0035).

The increase in OS was greater for patients who received 2 doses of VCN-01 and 4 or more cycles of gemcitabine/nab-paclitaxel SoC (n=34) compared with patients who received 4 or more cycles of gemcitabine/nab-paclitaxel SoC (n=29) [median OS 14.8 and 11.6 months respectively; HR=0.44, 95% CI: 0.21-0.92, p=0.046], suggesting that the second dose of VCN-01 (administered 3 months after the first dose) provides a meaningful additional benefit in this treatment subgroup.

On October 20, 2025, expanded mPDAC data from the VIRAGE Phase 2b trial (NCT05673811) were presented in oral communication at the ESMO 2025 Annual Congress, which took place in Berlin, Germany. Results from the VIRAGE Phase 2b trial included in the abstract for the presentation titled "VIRAGE trial: randomized Phase IIb, open-label, study of Nab-Paclitaxel and Gemcitabine with/without intravenous VCN-01 in Patients with Metastatic Pancreatic Cancer (mPDAC)" are set forth below:

112 patients were randomized. Patients in the modified intent to treat ("mITT") population received at least 1 dose of gemcitabine/nab-paclitaxel ("GA") standard of care chemotherapy (GA, Arm I) or VCN-01 (Arm II). Patients in the full analysis set ("FAS") population received at least 1 dose of gemcitabine/nab-paclitaxel SoC chemotherapy (GA; Arm I) or VCN-01 followed by at least 1 dose of GA (Arm II).

	mITT			FAS		
	Arm I (48)	Arm II (53)	HR (95% CI)	Arm I (48)	Arm II (48)	HR (95% CI)
OS mo.	8.6	10.6	0.69 (0.42-1.12) *P*=0.196	8.6	10.8	0.57 (0.34-0.96) *P*=0.055
PS mo.	4.6	5.6	0.63 (0.4-1.0) *P*=0.047	4.6	7.0	0.55 (0.34-0.88) *P*=0.011
DoR mo.	5.4	11.2	0.22 (0.08-0.62) *P*=0.004	5.4	11.2	0.22 (0.08-0.62) *P*=0.004
ORR	31.3%	35.8%		31.3%	39.6%	
mo. months						

Definitions -mo. (Months). OS (overall survival). PS or PFS (progression free survival). DoR (duration of response). ORR (objective response rate). HR (hazard ratio). CI (confidence interval).

Compared to patients who started GA cycle 4 alone (Arm I), patients who received 2 VCN-01 doses and started GA cycle 4 (Arm II) showed greater improvement in OS (14.8 vs 11.6 months; HR 0.44; 95% CI 0.21 - 0.92; *P*=0.046) and PFS (11.2 vs 7.4 months; HR 0.48; 95% CI 0.25 - 0.91; *P*=0.017). VCN-01 administration was well tolerated. All VCN- 01-related serious adverse events (n=13) were resolved, the most common being flu-like symptoms (13,2%), transaminase increase (5.7%) and drug-induced liver injury (3.8%). Viral genome analysis confirmed the bioactivity of the second VCN-01 dose.

This study met its primary endpoints. Patients receiving VCN-01 + GA had improved OS, PFS and DoR compared to GA standard of care.

Design of the Phase 3 Trial of intravenous VCN-01 with nab-paclitaxel plus gemcitabine in patients with mPDAC

On December 29, 2025, we announced the receipt of additional Scientific Advice (the "Additional Scientific Advice") from the CHMP of the EMA on the design of a Phase 3 clinical trial of lead clinical candidate VCN-01 in combination with gemcitabine/nab-paclitaxel standard-of-care (SoC) chemotherapy for the first-line treatment of metastatic PDAC. CHMP advised that a potential future marketing authorization application (MAA) for VCN-01 in metastatic PDAC could be supported by Theriva's proposed clinical development strategy comprising a single, high-quality, double-blinded, randomized, placebo-controlled Phase 3 trial if it demonstrates a compelling benefit-risk ratio with VCN-01 plus gemcitabine/nab-paclitaxel SoC compared to gemcitabine/nab-paclitaxel SoC alone. The Additional Scientific Advice included agreement on the proposed sample size, and the use of an adaptive design to potentially optimize trial timelines and outcomes. Inclusion/exclusion criteria, primary endpoint (overall survival), secondary endpoints (including progression free survival, duration of response, and patient reported outcomes) were also accepted. Importantly, CHMP recognized the increased improvement in overall survival rate of patients receiving 2 doses of VCN-01 in the VIRAGE study, and agreed with the proposed dosing of VCN-01 and gemcitabine/nab-paclitaxel in repeated "macrocycles", enabling more than 2 doses of VCN-01 to be administered in the Phase 3 trial. They further suggested that more frequent dosing of VCN-01 could be considered. An End-of-Phase 2 meeting with the FDA is planned for first half of 2026, aiming to finalize the design of a pivotal multinational Phase 3 clinical trial in PDAC.

Retinoblastoma

Retinoblastoma is a tumor that originates in the retina and it is the most common type of eye cancer in children. It occurs in approximately 1/14,000 - 1/18,000 live newborns and accounts for 15% of the tumors in the pediatric population < 1 year old. The average age of pediatric patients at diagnosis is 2, and it rarely occurs in children older than 6. In the US, retinoblastoma shows an incidence rate of 3.3 per 1,000,000 with only about 200 to 300 children diagnosed per year according to the American Cancer Society. Bilateral

retinoblastoma (Rb1 germinal mutation) represents 25-35% of the cases while unilateral retinoblastoma (sporadic mutation) accounts for 65-75%. While retinoblastoma is a highly curable disease in the US, with a current disease-free survival rate of >95%, the clinical challenge for those who treat retinoblastoma is to preserve life and to prevent the loss of an eye, blindness and other serious effects of treatment that reduce the patient's life span or the quality of life. In addition, children with retinoblastoma have been more likely to lose their eye and die of metastatic disease in low-resource countries.

Current treatments are not without significant morbidity, which may include visual impairment and severe cosmetic deformity secondary to enucleation and/or irradiation of the orbital region. The use of intravenous chemotherapy and more recently intra-arterial and intravitreal chemotherapy have resulted in a significantly greater number of eyes preserved with fewer long-term effects compared to past treatments such as external radiation therapy. However, allowing patients with advanced intraocular disease to be treated conservatively, led to the appearance of a subgroup of patients with advanced intraocular disease who relapsed after an initial response. Most of these cases include those patients who present gross vitreous or subretinal seeding. Once the aforementioned treatments are exhausted, these patients rarely manage to preserve the eyes and vision and must be enucleated. The ocular preservation rate of these eyes with advanced disease is still less than 50%.

In February 2022, the FDA granted Orphan Drug designation to VCN-01 for the treatment of retinoblastoma.

Phase 1 Trial of intravitreal VCN-01 (zabilugene almadenorepvec) in patients with retinoblastoma

During the third quarter of 2017, VCN entered into a Clinical Trial Agreement with Hospital Sant Joan de Déu (Barcelona, Spain) to conduct an investigator sponsored Phase 1 clinical study evaluating the safety and tolerability of two intravitreal injections of VCN-01 in patients with intraocular retinoblastoma refractory to systemic, intra-arterial or intravitreal chemotherapy, or radiotherapy, in whom enucleation was the only recommended treatment (NCT03284268). Patients received two intravitreal injections of VCN-01, 14 days apart, at a dose of either 2×10^9 vp/eye (n=1) or 2×10^{10} vp/eye (n=8). The trial has concluded and the clinical study report has been completed.

On April 23, 2024, we announced positive topline data from this study, with agreement by the study Monitoring Committee that the study had a positive outcome. Per the terms of the clinical trial agreement, the determination by the study Monitoring Committee that the study had a positive outcome means we received an exclusive, worldwide technology license, and related patents from Hospital Sant Joan de Déu for the treatment of pediatric patients with advanced retinoblastoma and we are obligated to pay to Hospital Sant Joan de Déu the amount of three hundred twenty thousand, two hundred and sixty five Euros (€320,265) or approximately $334,000, half of which has been paid and the remaining half is expected to be paid upon invoice receipt.

A pre-Investigational New Drug ("IND") meeting with the FDA was held on December 19, 2023 to discuss the path forward for VCN-01 as an adjunct to chemotherapy in pediatric patients with advanced retinoblastoma. The FDA provided some guidance on the potential endpoints and patient population for an advanced clinical trial and encouraged submission of a formal protocol under a US IND in order to provide more detailed commentary.

On July 30, 2024, we received notice from the FDA that we had been granted Rare Pediatric Drug Designation ("RPDD") for VCN-01 for the treatment of retinoblastoma. The FDA grants RPDD for rare diseases (fewer than 200,000 affected persons in the United States) that are serious and life-threatening and primarily affect children ages 18 years or younger. If a Biologics License Application for VCN-01 for the treatment of retinoblastoma is approved by the FDA by September 30, 2029, we may be eligible to receive a Priority Review Voucher.

On October 11, 2024, the European Commission adopted the EMA recommendation to grant Orphan Medicinal Product Designation to VCN-01 for the treatment of retinoblastoma and the European Commission confirmed the designation under Regulation No 141/2000 of the European Parliament and of the Council.

On May 27, 2025, we announced the presentation of the final data from an investigator-sponsored Phase 1 study of VCN-01 (zabilugene almadenorepvec) in refractory retinoblastoma patients in a poster presented by Dr. Jaume Català-Mora, Pediatric Ophthalmologist, Sant Joan de Déu-Barcelona Children's Hospital at the 2025 ASCO annual meeting. Based on the study results, it was concluded that VCN-01 was well tolerated, after 2 intravitreal administrations at 2E10 vp/eye. The most frequently reported treatment-related adverse events were Grade 1 or 2-uveitis being the most common adverse event and one patient with Grade 3 uveitis who did not receive the second dose because of medical decision and also experienced glaucoma requiring treatment. No systemic toxicities occurred. There were no dose limiting toxicities and no ocular or systemic toxicities greater than Grade 3 during the evaluation period. Final findings include the following:

- Some degree of ocular inflammation and associated turbidity was observed after VCN-01 injection. Inflammation was managed, and vitreous haze improved in some cases, using pre-emptive oral and/or topical steroids.
- VCN-01 did not cause retinal toxicity, and selective VCN-01 replication in retinoblastoma cells was observed by immunohistochemical analysis. VCN-01 caused reversible changes in electroretinograms associated to turbidity.
- Replication of VCN-01 was detected over time within retinoblastoma tumors but was not observed in healthy tissue.
- Intravitreal VCN-01 demonstrated promising antitumor activity:
    - Five patients presented a partial response, three presented stable disease and one, progressive disease
    - The eyes of 3 out of 5 patients with partial response were preserved with vision after receiving eye-conservative therapy (follow-up 12-49 months)

VCN-01 (zabilugene almadenorepvec) in combination with Immunomodulatory therapeutics

Based on the clinical and pre-clinical data described below, we believe that the administration of VCN-01, can elicit an anti-tumor immune response that could potentiate the effects of VCN-01 and co-administered therapeutics. Biopsies from the Phase 1 trial of PDAC patients administered intravenous VCN-01 demonstrated lymphocyte (CD8+) infiltration and modulated levels of immune markers in tumors, including an induction of the PD1/PD-L1 expression in tumor tissue from some of the patients. Preclinical experiments demonstrated that VCN-01 significantly increased extravasation of an anti-PD-L1 antibody into subcutaneous xenograft tumors compared to non-treated (PBS) tumors and also that PH20 hyaluronidase improves the ingress of T-cells in animal models. We believe that the administration of VCN-01 into the tumor may help to overcome the observed resistance to PD-L1 checkpoint inhibitors and to mesothelin-directed CAR-T cells.

Phase 1 Trial of intravenous VCN-01 (zabilugene almadenorepvec) in Combination with Durvalumab in Subjects with Recurrent/ Metastatic SCCHN

In February 2019, VCN entered into a Clinical Trial Agreement with Catalan Institute of Oncology (ICO) (Spain) to conduct an investigator sponsored Phase 1 clinical study to evaluate the safety, tolerability and RP2D of a single intravenous injection of VCN-01 combined with durvalumab in two administration regimens: VCN-01 concomitantly with durvalumab, or sequentially with durvalumab starting two weeks after VCN-01 administration (NCT03799744). The study was also designed to evaluate whether VCN-01 treatment can re-sensitize PD-(l)-1 refractory tumors to subsequent anti-PD-L1 therapy. Durvalumab is a human monoclonal antibody ("mAb") of the immunoglobulin G (IgG) 1 kappa subclass that inhibits binding of PD-L1. It is marketed as IMFINZI® by AstraZeneca/MedImmune, who supplied the product for its use in the clinical study. This Phase I trial was a multicenter, open label, dose escalation study in patients with histologically confirmed head and neck squamous cell carcinoma from specific sites: oral cavity, oropharynx, larynx or hypopharynx that is recurrent/metastatic (R/M) and not amenable to curative therapy by surgery or radiation. In addition, all patients should have undergone prior exposure to anti-PD-(L) 1 and progressed. Patients were entered at each dose level, according to a planned dose escalation schedule. The treatment was a single intravenous VCN-01 dose combined with concomitant intravenous durvalumab (MEDI4736) 1500 mg Q4W (Arm I) or durvalumab starting two weeks after VCN-01 administration ("sequential schedule"; Arm II). Patient recruitment into Arm I and Arm II was performed concurrently. Intravenous VCN-01 was administered to each patient only once during the trial at the VCN-01 dose level to which they were randomized. Durvalumab was administered Q4W until disease progression, unacceptable toxicity, withdrawal of consent, or another discontinuation criterion. Patient recruitment into the study was completed in February 2022 with a total of 18 patients enrolled. On September 5, 2022 we announced a presentation of initial data from this study in a poster at the ESMO Congress. The poster reported that treatment with VCN-01 was well tolerated when administered with durvalumab in the sequential schedule and the most common treatment-related adverse events were dose-dependent and reversible pyrexia, flu-like symptoms and increases in liver transaminases. Sustained blood levels of VCN-01 viral genomes and increased serum hyaluronidase levels were maintained for over six weeks and analysis of tumor samples showed an increase in CD8 T cells (a marker of tumor inflammation); upregulation of PD-L1; and downregulation of matrix-related pathways after VCN-01 administration. The trial has been completed and the clinical study report has been completed.

On October 16, 2023, we presented additional data from this study in a poster at the ESMO 2023 Congress held virtually and in Madrid, Spain from October 20-24, 2023. Key data and conclusions featured in the ESMO presentation include:

- 20 patients were enrolled with a median of 4 prior lines of therapy, from which six in the concomitant ("CS") (single dose of VCN-01 in combination with durvalumab on day 1) and 12 in the sequential ("SS") (single dose of VCN-01 on day -14 and durvalumab on day 1) were evaluable for response.
    - In the CS cohort at the 3.3×10^{12} viral particles (vp) dose, OS was 10.4 months.
    - In the SS cohort at the 3.3×10^{12}vp dose OS was 15.5 months, whereas in the SS cohort at the 1×10^{13} vp dose OS was 17.3 months.
    - 11 patients (61.1%) were alive >12 months (2 in CS; 5 in SS at 3.3×10^{12}vp, 4 in SS at 1×10^{13} vp).
    - In spite of the advanced stage of the disease, and a global objective response rate for the trial of 5.5%, most of the patients appeared to benefit from subsequent treatment, with 2 patients showing complete responses to palliative chemotherapy and at least one patient still alive 4 years after entering the study.
- Biological activity: Patients showed VCN-01 replication and increased serum hyaluronidase levels were maintained for over six weeks.
    - Observed an increase in CD8 T cells, a marker of tumor inflammation and an upregulation of PD-L1 in tumors.
    - Increase of PDL1-combined positive score (CPS; 16/21; p=0.013) and CD8 T-cells (12/21; p=0.007) from baseline were found in tumor biopsies.
    - There was a statistically significant correlation between OS observed in patients and CPS on day 8 (p=0.005).

Phase 1 Trial evaluating the safety and feasibility of huCART-meso cells when given in combination with VCN-01 (zabilugene almadenorepvec)

In July 2021, VCN entered into a Clinical Trial Agreement with the University of Pennsylvania (Philadelphia) to conduct an investigator sponsored Phase 1 clinical study to evaluate the safety, tolerability and feasibility of intravenous administration of VCN-01 in combination with lentiviral transduced huCART-meso cells (developed by the laboratory of Dr. Carl June) in patients with histologically confirmed unresectable or metastatic pancreatic adenocarcinoma and serous epithelial ovarian cancer (NCT05057715). This is a Phase 1 study evaluating the combination of VCN-01 when given in combination with huCART-meso cells in a dose-escalation design in two cohorts (N = 3-6), where patients receive VCN-01 as a single IV infusion (at $3.3x10^{12}$ or $1x10^{13}$ vp) on Day 0, followed by a single dose of $5x10^{7}$ huCART-meso cells on Day 14 via IV infusion. huCART-meso cells are modified T-cells targeting the mesothelin antigen, which is frequently expressed in multiple tumor types, particularly in pancreatic and ovarian cancers. Dr. June's previous clinical studies have shown that huCART-meso cells encounter significant challenges in the tumor microenvironment, including immunosuppressive cells and soluble factors as well as metabolic restrictions. Initial VCN-01 clinical data from the studies described above suggest that administration of VCN-01 may increase tumor immunogenicity and improve access of the huCART-meso cells to tumor cells. This Phase 1 study will evaluate the safety and tolerability of the VCN-01 huCART-meso cell combination and test the hypothesis that administration of VCN-01 may enhance the potential antitumor effects of the co-administered huCART-meso cells.

On July 8, 2022, we were notified that the first patient to be dosed with VCN-01 had passed the safety evaluation period in this study. On June 22, 2023, at their Cellicon Valley conference, and again at the Society for Immunotherapy of Cancer (SITC) meeting in San Diego, CA on November 3, 2023, and the International Oncolytic Virotherapy Conference (IOVC2023) in Calgary on November 13 2023, University of Pennsylvania investigators presented preliminary clinical safety and pharmacokinetic data from this study highlighting the feasibility of administering VCN-01 in sequence with huCART-meso cells in pancreatic and ovarian cancer patients. VCN-01 persistence was suggestive of tumor infection and active replication. The peak and duration of huCART-meso T cells in the peripheral blood as well as duration of stable disease in evaluable patients showed encouraging trends.

On October 16, 2024, at the 2024 Advancing Gene Therapy and Cell Therapies for Cancer conference by the American Society for Gene and Cell Therapy in Philadelphia, University of Pennsylvania investigators presented results from the Phase 1 trial of huCART-meso cells administered in combination with VCN-01 in patients with pancreatic and serous epithelial ovarian cancer. Safety was in line with expectations from monotherapy studies and $3.3x10^{12}$ was defined as the dose for further development. The C_{max} of huCART-meso cells showed some signs of enhancement in patients previously infused with VCN-01. 66.6% (4 out of 6) patients with measurable disease receiving huCART-meso after VCN-01 showed tumor shrinkage, indicating a promising trend in disease stabilization in patients receiving huCART-meso and VCN-01 compared to either agent alone.

On November 19, 2024, we were notified by the investigators that they would not continue with the present clinical trial, instead preferring to focus on advancement of a next-generation mesothelin-specific CAR-T. This new CAR-T could potentially be evaluated in combination with VCN-01 in a future clinical trial. The trial is active, although not recruiting as treated patients are still on survival follow - up.

Phase 1 Trial evaluating the intravenous administration of VCN-01 (zabilugene almadenorepvec) in patients prior to surgical resection of high-grade brain tumors

In the second quarter of 2021, VCN entered into a Clinical Trial Agreement with the University of Leeds (UK) to sponsor a proof-of-concept Phase 1 clinical study to evaluate whether intravenously administered VCN-01 can cross the blood-brain barrier and infect the target brain tumor. This is an open-label, non-randomized, single center study of VCN-01 given intravenously at a dose of $1x10^{13}$ virus particles to patients prior to planned surgery for recurrent high-grade primary or metastatic brain tumors. We believe that the intravenous delivery of anti-cancer therapy to brain tumors, if effective, may enable the treatment of systemically disseminated brain metastases and may allow for reduction in the need to use neurosurgery to administer the drugs. This study aims to assess the presence of VCN-01 within the resected surgical specimen after systemic VCN-01 delivery and determine the safety of intravenous VCN-01 in patients with recurrent high-grade glioma or brain metastases. By confirming the presence of VCN-01 in high grade brain tumors following intravenous delivery, we believe this study may pave the way for larger trials to study VCN-01 efficacy, both as a monotherapy and in combination with PD-1/PD-L1 blockade. This trial has already received approval from Medicines & Healthcare Products Regulatory Agency (MHRA) from UK Government.

On January 9, 2023, we issued a press release announcing that the first patient was dosed in this study. Recruitment is on-going but challenging.

On May 12, 2025, a protocol amendment was submitted for this trial to MHRA and on July 8, 2025 we were notified by the investigator that the protocol amendment had been approved.

VCN-01 (zabilugene almadenorepvec) + Topoisomerase Inhibitors

On May 10, 2024, we presented non-clinical data describing enhanced anti-tumor effects in human pancreatic cancer xenograft-bearing mice treated with lead product candidate VCN-01 and liposomal irinotecan in a poster at the 27th American Society of Gene and Cell Therapy (ASGCT) 2024 Congress held in Baltimore (Maryland) from May 7-11, 2024. These data support the potential synergy of VCN-01 and additional first-line pancreatic cancer chemotherapy regimens FOLFIRINOX and NALIRIFOX. Key findings reported in the poster include:

- The combination of VCN-01 + topoisomerase I (topo1) inhibitors, such as liposomal irinotecan, has a tolerable toxicity profile and may improve efficacy in the treatment of human pancreatic cancer.
- Viral protein expression was increased in human pancreatic cancer cell lines when they were exposed to topo1 inhibiting chemotherapeutics, irinotecan, its active metabolite, SN-38, and topotecan.
- Synergy of VCN-01 plus liposomal irinotecan was observed in animals bearing subcutaneous human pancreatic tumors.
    - In human pancreatic mouse xenograft models, treatment with VCN-01 at a dose of 4x1010 vp or liposomal irinotecan alone (at both the 10 mg/kg and 5 mg/kg doses) resulted in significant tumor growth inhibition compared to saline.
    - Combination therapy with VCN-01 + liposomal irinotecan at either dose displayed significantly reduced tumor growth compared to each treatment alone.
    - qPCR analyses performed on tumors collected at end of study confirmed the presence of viral genomes, indicating ongoing transcriptional activity of VCN-01, which is consistent with viral replication for several days after administration.

We believe that intravitreal coadministration of VCN - 01 with topotecan may provide a new treatment option for children with refractory retinoblastoma and vitreous seeds, which remains an unmet medical need in patients with this rare disease. Discussions are on - going with clinicians and key opinion leaders to define a clinical protocol for the VCN - 01 + topotecan combination in this patient population.

VCN-X Next Generation OVs and Albumin Shield™ Technology

We have also conducted research and development activities for next-generation oncolytic adenoviruses (termed VCN-X) with novel therapeutic payloads and structural modifications designed to increase tumor cell killing and improve systemic virus pharmacokinetics. Preclinical proof-of-concept has been established with VCN-11, which has been engineered to contain all the features of VCN-01 as well as an additional modification to include an albumin binding domain (ABD) in the virus capsid. The virus capsid is the target for neutralizing NAbs that are generated by the host immune system to destroy circulating viruses. The presence of an ABD, however, blocks the binding of most neutralizing antibodies, which allows the virus to reach the tumor following intravenous administration. This “Albumin Shield” works because human blood contains a large amount of albumin to coat the ABD-containing virus. Importantly, this coating of albumin appears to be displaced after the virus reaches tumor cells to infect them. In pre-clinical mouse studies to test the functionality of the “Albumin Shield”, mice pre-immunized with virus are able to completely neutralize an unmodified OV because they have a large concentration of Nabs in their blood. By contrast, viruses such as VCN-11 that contain the ABD are not neutralized and retain their ability to infect and destroy tumor cells. We believe the results with VCN-11 support the application of the Albumin Shield technology in our VCN-X program to advance treatments for tumors in which rapid multi-dosing may be beneficial. VCN-12 is currently the focus of our preclinical studies.

In March 2021, preclinical data obtained with VCN-11 was published (J Control Release. 2021 Apr 10;332:517-528), showing that the ABD-containing virus induced 450 times more cytotoxicity in tumor cells than in normal cells. Hyaluronidase production was confirmed by measuring the activity of the PH20 enzyme with a hyaluronic acid-degradation assay, and by measuring PH20 activity in VCN-11 infected tumors in vivo. The ABD-containing virus evaded NAbs from different sources and tumor levels of virus were demonstrated in the presence of high levels of NAbs in vivo, whereas the control virus without ABD was neutralized. VCN-11 showed a low toxicity profile in athymic nude mice and Syrian hamsters, allowing treatments with high doses and fractionated administrations without major toxicities (up to $1.2x10^{11}$vp/mouse and $7.5x10^{11}$vp/hamster). ALT levels were increased on day 3 within an acceptable range that returned to normal levels by day 9. Fractionated intravenous administration of the ABD-containing virus (splitting the dose into two portions

administered 4 h apart) appeared to improve virus circulation kinetics and increase tumor levels. Antitumor efficacy was observed in the presence of NAbs against Ad5 and the ABD-containing virus.

In May 2022, we presented data at the 25th Annual Meeting of the ASGCT. The presentation included preclinical results showcasing the potential of the Albumin Shield Technology to effectively target tumors after intravenous re-administration, even in the presence of high level NAbs, with no major toxicities observed. Our internal VCN-X discovery programs are currently evaluating new oncolytic viruses armed with alternative payloads that may increase antitumor efficacy.

In October 2025, Dr. Ramón Alemany, co-founder of VCN (now Theriva Biologics S.L.) and Head of the Immunotherapy and Virotherapy Group at the ProCURE Program of the Catalan Institute of Oncology (ICO) and the Oncobell Program of the Biomedical Research Institute of Bellvitge (IDIBELL) in Barcelona, presented new mechanistic and preclinical data for VCN-12, a next generation oncolytic adenovirus selected from our VCN-X discovery program at the 32nd Annual Congress of the European Society of Gene & Cell Therapy (ESGCT) in Seville, Spain. VCN-12 is derived from lead clinical product VCN-01 (zabilugene almadenorepvec) and is armed with additional transgenes designed to improve tumor cell lysis, enhance stroma degradation, and augment the antitumor immune response. VCN-12 uses the same virus capsid as our lead clinical candidate VCN-01 (zabilugene almadenorepvec), but includes modifications intended to (i) increase stroma degradation by replacing human hyaluronidase PH20 with the more active bee hyaluronidase; and (ii) increase tumor cell lysis by expressing the pore forming protein parasporin-2 to enable both cytotoxic and immunogenic cell death. Parasporin-2 expression is expected to destroy both infected and surrounding uninfected tumor cells and stimulate a strong overall antitumor immune response and reduce viral immunodominance. Data presented by Dr. Alemany support the proposed VCN-12 mechanisms of action. VCN-12 showed increased cell killing compared to VCN-01 in a variety of cancer cell models in vitro. VCN-12 also displayed higher levels of hyaluronidase activity. In animal studies, intravenous VCN-12 had a similar toxicity profile to VCN-01 in immunodeficient mice bearing human tumor xenografts. Intratumoral VCN-12 significantly reduced tumor growth compared to VCN-01 in immunocompetent hamsters bearing HP-1 pancreatic tumors. The antitumor effect of VCN-12 was observed in both the injected tumors and second tumors-implanted 4-days later but not injected. Complete tumor regression of the first tumor was observed in two of nine hamsters and the second implanted tumor did not grow in these animals. VCN-12 appeared to stimulate a persistent immune response that prevented the establishment of tumors in these two complete responders when they were implanted with HP-1 cells 43 days after VCN-12 treatment. Further preclinical studies are planned to elaborate these initial findings.

THERICEL suspension cell lines for viral manufacturing

The THERICEL program is advancing a proprietary A549 suspension cell line for use in the manufacture of viral therapeutics. These cells are entering feasibility studies to support significant scale - up and potential Phase 3 GMP manufacture of VCN-01 (zabilugene almadenorepvec) for use in clinical trials. The use of the THERICEL suspension cells is expected to increase the efficiency and significantly reduce the cost of manufacture for VCN - 01 and other viral therapies.

We also have a Spanish government funded collaboration with the Universitat Autònoma de Barcelona to adapt the THERICEL suspension cell platform for the clinical manufacture of adeno - associated virus (“AAV”) therapies. If successful, adaptation of the THERICEL platform to AAV manufacture will provide an opportunity for potential commercial collaborations in the manufacture of a range of gene therapy products.

Our Current Gastrointestinal (GI) and Microbiome-Focused Product Candidates

SYN-004 (ribaxamase) and SYN-020 are focused on the GI tract and the gut microbiome, which is home to billions of microbial species and composed of a natural balance of both "good" beneficial species and potentially "bad" pathogenic species. When the natural balance or normal function of these microbial species is disrupted, a person's health can be compromised. All of our programs have been supported by a robust patent estate. As part of our strategic transformation into an oncology focused company, we (i) entered into the Rasayana License Agreement with Rasayana in February 2026, pursuant to which we granted Rasayana an exclusive worldwide license to research, develop, manufacture and commercialize any product related to or deriving from our SYN-020 asset, and (ii) we are exploring value creation options for our SYN - 004 asset, including out - licensing or partnering as we do not intend to further develop SYN-004 without receipt of grant funding or funding through a partnership or other collaboration.

SYN-004 (ribaxamase) — Prevention of antibiotic-mediated microbiome damage, thereby preventing overgrowth and infection by pathogenic organisms such as Clostridioides difficile infection (CDI) and vancomycin resistant Enterococci (VRE), and reducing the incidence and severity of acute graft-versus-host disease (aGVHD) in allogeneic HCT recipients

SYN-004 (ribaxamase) is a proprietary oral capsule prophylactic therapy designed to degrade certain IV beta-lactam antibiotics excreted into the GI tract and thereby maintain the natural balance of the gut microbiome. Preventing beta-lactam damage to the gut microbiome has a range of potential therapeutic outcomes, including prevention of CDI, suppression of the overgrowth of pathogenic species (particularly antimicrobial-resistant organisms) and potentially reducing the incidence and/or severity of aGVHD in allogeneic hematopoietic cell transplant (HCT) patients. SYN-004 (ribaxamase) 75 mg capsules are intended to be administered orally while patients are administered certain IV beta-lactam antibiotics. The capsule dosage form is designed to release the SYN-004 (ribaxamase) enzyme into proximal small intestine, where it has been shown to degrade beta-lactam antibiotics in the GI tract without altering systemic antibiotic levels. Beta-lactam antibiotics are a mainstay in hospital infection management and include the commonly used penicillin and cephalosporin classes of antibiotics.

Clostridioides difficile Infection

Clostridioides difficile (formerly known as *Clostridium difficile* and often called *C. difficile* or CDI) is a leading type of hospital acquired infection and is frequently associated with IV beta-lactam antibiotic treatment. The Centers for Disease Control and Prevention (CDC) identified *C. difficile* as an "urgent public health threat," particularly given its resistance to many drugs used to treat other infections. CDI is a major unintended risk associated with the prophylactic or therapeutic use of IV antibiotics, which may adversely alter the natural balance of microflora that normally protect the GI tract, leading to *C. difficile* overgrowth and infection. Other risk factors for CDI include hospitalization, prolonged length of stay (estimated at 7 days), underlying illness, and immune-compromising conditions including the administration of chemotherapy and advanced age.

Limitations of Current Treatments and Market Opportunity

CDI is a widespread and often drug- resistant infectious disease. Approximately 20% of patients who have been diagnosed with CDI experience a recurrence of CDI within one to three months. Furthermore, controlling the spread of CDI has proven challenging, as the *C. difficile* spores are easily transferred to patients via normal contact with healthcare personnel and with inanimate objects. There is currently no vaccine or approved product for the prevention of primary (incident) CDI. The current standard of care for primary CDI, as outlined by the Infectious Disease Society of America (IDSA), is to treat with powerful antibiotics such as fidaxomicin or vancomycin. Prolonged use of fidaxomicin and vancomycin has been shown to further exacerbate damage to the gut microbiome, leading to increased risk of CDI recurrence as well as the emergence of pathogenic and antimicrobial-resistant (AMR) organisms, such as vancomycin-resistant enterococci (VRE). AMR is a serious global threat and one which world leaders have begun to take action against. According to the European Society of Clinical Microbiology and Infections Disease (ECCMID), failure to address AMR could lead to a potential "antibiotic Armageddon", resulting in 10 million deaths worldwide by 2050 and may cost as much as $100 trillion in worldwide economic output.

The latest CDC estimates found the crude overall incidence rate of CDI in the United States to be 117.2 cases per 100,000 persons (approximately 392,000 patients based on the estimated US population at the end of 2023) with a higher rate of community associated compared to healthcare associated infection (CDC Emerging Infections Program Healthcare-Associated Infections–Community Interface Report Clostridioides difficile Infection Surveillance, 2023. https://www.cdc.gov/healthcare-associated-infections/media/pdfs/2023-CDI-Report-508.pdf).

Phase 1a and 1b Clinical Trial Pharmacokinetic Data

In March 2015, we reported supportive pharmacokinetic data from a Phase 1a clinical trial (40 participants), which suggested that SYN-004 (ribaxamase) should have no effect on the IV antibiotic in the bloodstream, allowing the antibiotic to fight the primary infection. In February 2015, we reported supportive topline results from a subsequent Phase 1b clinical trial (24 participants) of escalating doses of oral SYN-004 (ribaxamase), with no safety or tolerability issues reported at dose levels and dosing regimens that were equivalent to or exceeded those expected to be studied in subsequent clinical trials.

Two Phase 2a Clinical Trials: Topline Results

In December 2015, we reported supportive topline results from our first Phase 2a clinical trial of SYN-004 (ribaxamase, NCT02419001). The study demonstrated that SYN-004 (ribaxamase) successfully degraded IV ceftriaxone in the chyme of ten participants with ileostomies without affecting the levels of ceftriaxone in the bloodstream. In May 2016, we reported supportive topline results from a second Phase 2a clinical trial of SYN-004 (ribaxamase) in 14 healthy participants with functioning ileostomies administered IV ceftriaxone with and without oral SYN-004 (ribaxamase) (NCT02473640). This second study demonstrated that the 150 mg dose of SYN-004 (ribaxamase), both alone and in the presence of the proton pump inhibitor (PPI), esomeprazole, degraded ceftriaxone excreted into the chyme resulting in ceftriaxone levels that were low or not-detectable. Ceftriaxone plasma concentrations in participants of the second study were not altered by SYN-004 (ribaxamase) in the presence or absence of an oral PPI, suggesting limited drug-drug interactions. The 150 mg dose of SYN-004 (ribaxamase) was well tolerated by all participants in this clinical trial.

Phase 2b Proof of Concept Clinical Trial Design & Results

On January 5, 2017, we announced positive topline data from our Phase 2b proof-of-concept clinical trial (412 participants-206 per group; NCT02563106) intended to evaluate the ability of SYN-004 (ribaxamase) to prevent CDI, CDAD (*C. difficile*-associated diarrhea) and AAD (antibiotic-associated diarrhea) in patients hospitalized for a lower respiratory tract infection and receiving IV ceftriaxone. Results from this study demonstrated that SYN-004 (ribaxamase) achieved its primary endpoint of significantly reducing CDI. Preliminary analysis of the data indicated seven confirmed cases of CDI in the placebo group compared to two cases in the SYN-004 (ribaxamase) treatment group. Patients receiving SYN-004 (ribaxamase) achieved a 71.4% relative risk reduction (p-value=0.045) in CDI rates compared to patients receiving placebo. SYN-004 (ribaxamase) treated patients also demonstrated a significant reduction in new colonization by vancomycin-resistant enterococci (VRE) compared to placebo (p-value=0.002). Results from this trial also demonstrated that patients administered ribaxamase in conjunction with IV-ceftriaxone demonstrated comparable cure rates (approximately 94%) for the treatment of primary infection compared to the placebo group. Results from this trial also demonstrated that the percentage of subjects reporting at least one treatment emergent adverse event (TEAE) was similar between SYN-004 (ribaxamase) and placebo treatment groups (40.8% vs 44.2%). Adverse events reported during this trial were comparable between treatment and placebo arms. Serious adverse events (SAEs) in the treatment arm, including fatal AEs, which exceeded those in the placebo arm, were not considered drug-related by investigators at the clinical sites, or by an independent third-party, each of whom determined SAEs were attributable to disparities in the underlying health and comorbidities between the groups.

On October 6, 2016 we were awarded a government contract in the amount of $521,014 by the CDC's Broad Agency Announcement (BAA) 2016-N-17812 to examine changes in the gut resistome of patients in our Phase 2b clinical study. Data generated under this contract are consistent with SYN-004's (ribaxamase) mode of action of preserving the normal gut flora by degrading ceftriaxone in the upper GI tract of study participants treated with SYN-004 (ribaxamase). The data further demonstrated that SYN-004 (ribaxamase) significantly reduced the loss of microbial diversity, reduced overgrowth of opportunistically pathogenic species (such as VRE), and reduced the emergence of AMR genes caused by ceftriaxone treatment in SYN-004 (ribaxamase) treated patients compared to placebo.

Future Potential Regulatory Strategy for Prevention of Primary CDI

On November 21, 2018, we announced results from our End-of-Phase 2 meeting with the FDA during which key elements of a Phase 3 clinical program were confirmed. Pursuant to the meeting, the FDA proposed criteria for Phase 3 clinical efficacy and safety which, if achieved, may support submission for marketing approval of SYN-004 (ribaxamase) on the basis of a single Phase 3 clinical trial. The

proposed SYN-004 (ribaxamase) Phase 3 clinical program entails a single, global, event-driven clinical trial with a fixed maximum number of approximately 4,000 patients for total enrollment and evaluates the potential efficacy and safety of ribaxamase in a broad patient population by enrolling patients with a variety of underlying infections treated with a range of IV beta-lactam antibiotics.

The proposed Phase 3 clinical trial incorporates co-primary safety and efficacy endpoints (mortality and the reduction in the incidence of CDI at one month after the last drug dose in the SYN-004 (ribaxamase) treatment group versus placebo, respectively). We expect the clinical development costs to complete this trial to be in excess of $80 million and anticipate initiating the Phase 3 clinical program only after securing additional potential financing via a strategic partnership.

Acute Graft-Versus-Host-Disease in Allogeneic Hematopoietic Cell Transplant (allogeneic HCT) Recipients & SYN-004 (ribaxamase)

In parallel with our clinical and regulatory efforts, we completed a Health Economics Outcomes Research ("HEOR") study, which was conducted to generate key insights on how we can expect Health Care Practitioners ("HCPs"), to evaluate patient access for SYN-004 (ribaxamase) while also providing a framework for potential reimbursement strategies. After evaluating findings from the study, we believe that there is significant potential value in exploring the development of SYN-004 (ribaxamase) in a narrower patient population where the incidence of the disease endpoint is high and the clinical development may be less costly.

We believe allogeneic hematopoietic cell transplant ("HCT") recipients, who have a very high risk of CDI, VRE colonization and potentially fatal bacteremia, and acute-graft-vs-host disease ("aGVHD"), represent such a patient population. Published literature has demonstrated a strong association between these adverse outcomes and microbiome damage caused by IV beta-lactam antibiotics in these patients. Approximately 80-90% of HCT recipients receive IV beta-lactam antibiotics to treat febrile neutropenia. Penicillins and cephalosporins are first-line therapies in the USA and EU, whereas carbapenems are first-line in China. Antibiotic-mediated damage to the gut microbiome is strongly associated with GVHD, bloodstream infections, VRE bacteremia, transplant relapse, and increased mortality in HCT recipients, raising concern over the spectrum of antibiotics used during HCT.

CDI occurs in up to 31% of HCT patients and is associated with aGVHD and increased mortality. aGVHD occurs in 30-60% of allogeneic HCT recipients and is recognized as a primary contributor to morbidity and mortality in this patient population. The most recent available data indicate approximately 8,000 reported allogeneic HCT procedures each year in the USA, 19,800 procedures in Europe, 12,700 in China, and 3,500 in Japan. First-line treatments for aGVHD fail in more than 50% of patients and 2-year survival in patients with steroid refractory aGVHD is only 20%. At least one U.S. study found allogeneic HCT recipients who developed aGVHD had 3-times higher in-hospital mortality and almost 2-fold higher median hospital costs than patients who did not develop aGVHD. It has been reported that in-patient costs for allogeneic HCT in the USA range from $180,000-$300,000 depending on the disease severity. VRE infection is a persistent problem in HCT patients and VRE colonization after HCT has been associated with decreased patient survival.

Phase 1b/2a Clinical Study in Allogeneic HCT Recipients

In August 2019, we entered into a Clinical Trial Agreement (CTA) with the Washington University School of Medicine (Washington University) to conduct a Phase 1b/2a clinical trial of SYN-004 (ribaxamase). Under the terms of this agreement, we serve as the sponsor of the study and supply SYN-004 (ribaxamase). Dr. Erik R. Dubberke, Professor of Medicine and Clinical Director, Transplant Infectious Diseases at Washington University and a member of the SYN-004 (ribaxamase) steering committee serves as the principal investigator of the clinical trial in collaboration with his Washington University colleague Dr. Mark A. Schroeder, Associate Professor of Medicine, Division of Oncology, Bone Marrow Transplantation and Leukemia.

The Phase 1b/2a clinical trial is a single center, randomized, double-blinded, placebo-controlled clinical trial of oral SYN-004 (ribaxamase) in up to 36 evaluable adult allogeneic HCT recipients. The goal of this study is to evaluate the safety, tolerability and potential absorption into the systemic circulation (if any) of oral SYN-004 (ribaxamase; 150 mg four times daily) administered to allogeneic HCT recipients who receive an IV carbapenem or beta-lactam antibiotic to treat fever. Study participants were enrolled into three sequential cohorts administered a different study-assigned IV antibiotic. Each cohort seeks to complete eight evaluable participants treated with SYN-004 (ribaxamase) and four evaluable participants treated with placebo. Safety and pharmacokinetic data for each cohort will be reviewed by an independent Data and Safety Monitoring Committee, which will make a recommendation on whether to proceed to the next IV antibiotic cohort. The study will also evaluate potential protective effects of SYN-004 on the gut microbiome as well as generate preliminary information on potential therapeutic benefits and patient outcomes of SYN-004 in allogeneic HCT recipients.

To date, we have completed 2 of 3 cohorts (Cohorts 1 and 2) in this study. On September 27, 2022, we issued a press release announcing positive outcomes from the Data and Safety Monitoring Committee ("DSMC") review of results from the first Cohort and their recommendation that the study may proceed to enroll Cohort 2 in which study drug (SYN-004 or Placebo) is administered in combination with the IV beta-lactam antibiotic piperacillin/tazobactam. Initiation of the third cohort is dependent on potential grant funding.

On February 16, 2023 and April 13, 2023, we announced the presentation of safety and pharmacokinetic data from Cohort 1 and on October 3, 2024, we announced a positive outcome from the DSMC review of results from the second Cohort of our Phase 1b/2a randomized, double-blinded, placebo-controlled clinical trial of SYN-004 (ribaxamase) in allogeneic hematopoietic cell transplant ("HCT") recipients for the prevention of acute graft-versus-host-disease. Based on a review of the safety and pharmacokinetic data, the DSMC recommended that the study may proceed to enroll Cohort 3 in which study drug (SYN-004 or Placebo) will be administered in combination with the IV beta-lactam antibiotic cefepime. Based upon our current available funding and our focus on our clinical development of VCN-01 we do not anticipate that enrollment for the third cohort will commence unless we obtain grant funding, or find a licensee or partner to fund the SYN-004 development program.

SYN-020 — Oral Intestinal Alkaline Phosphatase (IAP)

SYN-020 is a quality-controlled, recombinant version of bovine Intestinal Alkaline Phosphatase (IAP) produced under cGMP conditions and formulated for oral delivery. The published literature indicates that IAP functions to diminish GI and systemic inflammation, tighten the gut barrier to diminish "leaky gut," diminish fat absorption, and promote a healthy microbiome. Despite its broad therapeutic potential, a key hurdle to commercialization has been the high cost of IAP manufacture which is commercially available for as much as $10,000 per gram. We believe we have developed technologies to traverse this hurdle and now have the ability to produce more than 3 grams per liter of SYN-020 and anticipate a cost of roughly a few hundred dollars per gram at commercial scale. Based on the known mechanisms as well as our own supporting animal model data, we initially intended to develop SYN-020 to mitigate the intestinal damage caused by radiation therapy that is routinely used to treat pelvic cancers. While we believe SYN-020 may play a pivotal role in addressing acute and long-term complications associated with radiation exposure to the GI tract, we have also explored the potential development of SYN-020 in large market indications with significant unmet medical needs. Such indications include celiac disease, non-alcoholic fatty liver disease ("NAFLD"), and indications to treat and prevent metabolic and inflammatory disorders associated with aging.

On June 29, 2021, we announced that enrollment, patient dosing and observation had been completed in the Phase 1, open-label, single ascending dose (" SAD") study of SYN-020. The SAD study enrolled 6 healthy adult volunteers into each of four cohorts with SYN-020 given orally as single doses ranging from 5 mg to 150 mg. The data demonstrated that SYN-020 maintained a favorable safety profile, was well tolerated at all dose levels, and no adverse events were attributed to the study drug. No SAEs were reported.

Phase 1 Clinical Multiple-Ascending-Dose Study

During the third quarter of 2021 we initiated a Phase 1 clinical study evaluating multiple ascending doses ("MAD") of SYN-020 (NCT05045833). The placebo-controlled, blinded study enrolled 32 healthy adult volunteers into four cohorts with SYN-020 administered orally in doses ranging from 5 mg to 75 mg twice daily for 14 days with a follow-up evaluation at day 35. Each cohort included six subjects who received SYN-020 and two who received placebo. On May 10, 2022, we announced positive safety data from the Phase 1 MAD study demonstrating that SYN-020 maintained a favorable safety profile and was well-tolerated across all dose levels. There were a few treatment-related adverse events, and all were mild (grade 1) and resolved without medical intervention. The most common adverse event, constipation, occurred in three out of 24 subjects in the treatment arm and in one out of eight subjects in the placebo arm. No adverse event led to discontinuation of the study drug and there were no serious adverse events. Additionally, fecal SYN-020 analyses verified intestinal bioavailability while plasma levels of SYN-020 were below the limit of quantitation in all samples at all timepoints verifying that SYN-020 was not absorbed into the systemic circulation.

The Phase 1 data from our SAD and MAD studies are intended to support the development of SYN-020 in multiple clinical indications including radiation enteritis, NAFLD, celiac disease, and diseases associated with aging.

Rasayana License Agreement

On February 17, 2026, we entered into the Rasayana License Agreement with Rasayana, pursuant to which we granted Rasayana an exclusive worldwide license with the right to grant sublicenses to research, develop, manufacture and commercialize any Product (as such term is defined in the Rasayana License Agreement), which includes SYN-020, comprising, containing, or covered by the Licensed IP (as such term is defined in the Rasayana License Agreement) and/or devised, developed, or produced using the Licensed IP. Under the terms and conditions of the Rasayana License Agreement, Rasayana has agreed to use commercially reasonable efforts to meet certain specified development milestones with respect to the Products. Additionally, pursuant to the terms of the Rasayana License Agreement, Rasayana will assume all responsibility and costs for the development and commercialization of the Products. Accordingly, going forward, we do not expect to continue to conduct research and development activities, including conducting further clinical studies, with respect to SYN-020, and do not expect to incur material expenditures in connection therewith.

As consideration for the license, on February 17, 2026, we received an upfront payment of $300,000 from Rasayana. In addition, we are entitled to receive from Rasayana development milestone payments of up to an aggregate of $16.0 million and sales milestone payments of up to an aggregate of $22.0 million upon achievement of certain development and net sales milestones with respect to Products. In addition, during the Royalty Term (as such term is defined in the Rasayana License Agreement), we are entitled to receive tiered royalties ranging from low to mid single digits on net sales of a Product. We will also be entitled to receive a certain percentage of any Sublicense Revenue (as such term is defined in the Rasayana License Agreement) received by Rasayana or its affiliates.

Intellectual Property

Our success depends in part on our ability to obtain and maintain proprietary protection for our product candidates and other discoveries, inventions, trade secrets and know-how that are critical to our business operations. Our success also depends in part on our ability to operate without infringing the proprietary rights of others, and in part, on our ability to prevent others from infringing our proprietary rights.

We rely primarily on a combination of patent, copyright, trademark, and trade secret laws, as well as contractual provisions with employees and third parties, to establish and protect our intellectual property ("IP") rights. All of our programs are supported by a robust patent estate. In total, Theriva Biologics has over 135 U.S. and foreign patents and over 50 U.S. and foreign patents pending. VCN, through assignment or exclusive licenses, controls over 50 U.S. and foreign patents and over 15 U.S. and foreign patents pending.

The SYN-004 (ribaxamase) program is supported by IP that is assigned to Theriva Biologics, namely U.S. and foreign patents (in most major markets, e.g. Europe (including Germany, Great Britain and France), Japan, China and Canada, among others) and U.S. and foreign patents pending (in most major markets, e.g. Europe (including Germany, Great Britain and France), Japan, China and Canada, among others). For instance, U.S. Patent Nos. 8,894,994 and 9,587,234, which include claims to compositions of matter and pharmaceutical compositions of beta-lactamases, including SYN-004 (ribaxamase), have patent terms to at least 2031. Further, U.S. Patent 9,301,995 and 9,301,996, both of which will expire in at least 2031, cover various uses of beta-lactamases, including SYN-004 (ribaxamase), in protecting the microbiome, and U.S. Patent Nos. 9,290,754, 9,376,673, 9,404,103, 9,464,280, and 9,695,409 which will expire in at least 2035, covers further beta-lactamase compositions of matter related to SYN-004 (ribaxamase).

The SYN-020 (oral intestinal alkaline phosphatase (IAP)) program is supported by IP that is assigned to Theriva Biologics, namely U.S. and foreign patents and patent applications (in many major markets, e.g. Europe, China, Japan, Korea, Canada, and Australia). These patents and patent applications, which cover various formulations, medical uses and manufacture of SYN-020, are expected to expire in 2038-2040, without taking potential patent term extensions or patent term adjustment into account. All such patents were licensed to Rasayana pursuant to the Rasayana Agreement entered into in February 2026.

The VCN-01 (zabilugene almadenorepvec) and Albumin Shield programs are supported by U.S. and foreign patents and patent applications that are either assigned to VCN or exclusively licensed from IDIBELL, ICO, and Hospital Sant Joan de Déu in Barcelona. The patents and patent applications include U.S. patents and foreign patents (in most major markets, e.g. Europe, China, Japan, Korea, Canada, Israel, Mexico, Russia, and Australia) and U.S. and foreign patents pending (in most major markets, e.g. Europe, China, Korea, Canada, Mexico, and India). The patents and patent applications cover compositions of matter and pharmaceutical compositions of oncolytic adenoviruses together with combination with other agents and various medical uses of the same. For instance, U.S. Patent No. 10,316,065, which expires in 2030 without taking potential patent term extensions or patent term adjustment into account, provides composition of matter and pharmaceutical composition coverage for a genus of engineered oncolytic adenovirus suitable for the treatment of solid tumors. Other patents and patent applications, if granted, will provide protection to 2037 without taking potential patent term extensions or patent term adjustment into account.

Our goal is to (i) obtain, maintain, and enforce patent protection for our products, formulations, processes, methods, and other proprietary technologies, (ii) preserve our trade secrets, and (iii) operate without infringing on the proprietary rights of other parties worldwide. We seek, where appropriate, the broadest intellectual property protection for product candidates, proprietary information, and proprietary technology through a combination of contractual arrangements and patents.

Acquisition of VCN Biosciences, S.L. (now known as Theriva Biologics, S.L.)

On March 10, 2022, we completed our acquisition (the "VCN Acquisition") of all the outstanding shares of VCN (the "VCN Shares") from the shareholders of VCN pursuant to the terms of the Share Purchase Agreement ("Purchase Agreement") that we entered into with VCN and the shareholders of VCN Biosciences, S.L. (the "Sellers") on December 14, 2021. Upon consummation of the Acquisition, VCN became our wholly owned subsidiary. As consideration for the purchase of the VCN Shares of capital stock, we paid $4,700,000 (the "Closing Cash Consideration") to Grifols Innovation and New Technologies Limited ("Grifols"), the owner of approximately 86% of the equity of VCN, and issued to the remaining Sellers an aggregate of 2,639,530 shares of our Common Stock (the "Closing Shares"), representing 19.99% of the outstanding shares of our Common Stock on December 14, 2021, the date of the Purchase Agreement. As additional consideration for the purchase of the VCN Shares held by Grifols, we also agreed to make the following milestone payments to Grifols:

Milestone Payments

US$3MM upon VCN-01 US IND Safe to Proceed PDAC (or other *first* indication), which payment was made in Q4 2022 upon attaining the milestone

US$2.75MM upon VCN-01 US IND Safe to Proceed – retinoblastoma ("RB", or other *second* indication)

US$3.25MM upon VCN-01 US first patient dosed– PDAC (or other *first* indication) after receipt of VCN-01 US IND Safe to Proceed for PDAC being informed, which payment was made in Q4 2023 upon attaining the milestone

US$3.25MM upon VCN-01 US first patient dosed – RB (or other *second* indication) after receipt of VCN-01 US IND Safe to Proceed for RB being informed

US$6MM upon VCN-01 US Phase 2 trial meets the primary endpoint or if a Phase 2 trial is not conducted and only a Phase 3 trial is conducted then upon a Phase 3 being initiated – PDAC (or other *first* indication), of which $1.0 million has been paid and the remaining $5.0 million payment has been deferred pending ongoing discussions with Grifols.

US$8MM upon VCN-01 Pivotal Trial meeting the primary endpoint or upon Submission of a Biologics License Application ('BLA")– RB (or other *second* indication)

US$12MM upon VCN-01 US Phase 3 trial meeting the primary endpoint or upon BLA Submission – PDAC (or other *first* indication)

US$16MM upon VCN-01 BLA Approval – PDAC (or other *first* indication)

US$16MM upon VCN-01 BLA Approval – RB (or other *second* indication)

Pursuant to the Purchase Agreement, at the Closing we assumed $2,400,000 of liabilities of VCN, which includes certain loans from the Spanish Government and the Catalan Government Agency.

The Purchase Agreement contains customary representations, warranties and covenants of the Sellers and us. Subject to certain customary limitations, the Sellers have agreed to indemnify us and our officers and directors against certain losses related to, among other things, breaches of their representations and warranties, certain specified liabilities and the failure to perform covenants or obligations under the Purchase Agreement.

Our Current Collaborations

IDIBELL Technology Transfer Agreement

On August 31, 2010, VCN entered into a Technology Transfer Agreement (the "Technology Transfer Agreement") with IDIBELL for the exclusive license of the right to use a Spanish patent number P200901201 titled "Oncolytic adenoviruses for treating cancer" which is co-owned by IDIBELL and ICO for the term of the patent. The Technology Transfer Agreement provides that IDIBELL is entitled to a low single digit percentage royalty on the income collected by VCN from the utilization of products derived from the licensed technology, prior to applying any value-added tax, if any, and low single digit percentage royalty on other income received by VCN arising from the use of the licensed technology, including income related to sublicenses of the licensed technology to third parties and advance payments or payments made for goals that were met and/or services associated with the licensed technology. The Technology Transfer Agreement terminates upon the expiration of the patent rights and is subject to early termination by either party in the event of a breach by the other party of its obligations thereunder. In addition, IDIBELL has the right to revoke the license if VCN ceases business activities for a continuous year or ceases to utilize the technology subject of the Technology Transfer Agreement, uses the technology in violation of the principals of IDIBELL or ICO or stops maintaining the patent licensed under the Technology Transfer Agreement

ICO Marketing License

On May 16, 2009, VCN entered into a Contract to Grant a Marketing License (the "ICO License Agreement") with ICO for a manufacturing and marketing license of a patent P200700665 titled "Adenovirus with mutations in the area of endoplasmic retention of protein E3-19k and their use in the treatment of cancer" in connection with a sublicense identified therein. The validity period of the license granted is unlimited with the only applicable limit being the patent's own validity. The ICO License Agreement provides that the ICO is entitled to a royalty of low double digit percentage of the net value of the income from the concession of the identified sublicense and low double digit percentage on other lump sums received thereunder. VCN and its sublicensees have an obligation to use all diligent and commercially reasonable efforts for the exploitation of the patent, otherwise, ICO may proceed to recover the license. The ICO License Agreement terminates upon the expiration of the patent rights and is subject to early termination by either party in the event of a breach by the other party of its obligations thereunder.

IDIBELL/ICO License Agreement

On March 4, 2016, VCN entered into a License Agreement (the "IDIBELL/ICO License Agreement") with IDIBELL and the ICO, for the exclusive license of the right to use a family of patents whose priority application is European patent application EP 14 38 2162.7 titled "Adenovirus comprising an albumin-binding moiety". The License Agreement provides that IDIBELL and ICO, as licensors, are entitled to share a low single digit percentage royalty on the annual Net Sales (as defined in the IDIBELL/ICO License Agreement) collected by VCN from the utilization of products derived from the licensed technology and a royalty on sublicensing income received from the licensed technology at a rate of: low double digit percentage during the first 3 years following the effective date of the agreement, mid - single digit percentage during the term of 3 to 7 years following the effective date and low single digit percentage thereafter. The IDIBELL/ICO License Agreement also provides for certain fixed payments, including a payment 25 days following the date of concession of the licensed patent in a minimum of three European jurisdictions and a payment 25 days following the date of concession of an American patent derived from the licensed patent. The IDIBELL/ICO License has an indefinite term subject to early termination (i) by mutual agreement of the parties; (ii) by licensor in the event of at least two successive breaches or three alternate breaches calculated annually of the obligation to pay any consideration; (iii) by VCN at its discretion due to certain patent infringements of rights protected by the patents or due to the absence of protection of the patent in any countries in the territory which is worldwide or (iv) in the event of a breach by the other party of its obligations thereunder which are not remedied within thirty (30) days. In addition, the licensors have the right to revoke the IDIBELL/ICO License Agreement if VCN during a continuous period of two years abandons its research or development activities of the licensed patent or activities aimed at exploitation of the resulting products, VCN has undertaken no marketing whatsoever during the term of the IDIBELL/ICO License Agreement or uses the patent licensed for purposes other those as set forth in the IDIBELL/ICO License Agreement.

Sant Joan De Déu Collaboration and License Agreement

On February 15, 2016, VCN entered into a Collaboration Agreement to Conduct a Clinical Trial and Grant an Operating License (the "Collaboration and License Agreement") with the Sant Joan De Déu Hospital (the "Hospital") and the Sant Joan De Déu Foundation (the "Foundation", and together with the Hospital, the "Institution") regarding the conduct of a clinical trial to evaluate the safety and activity of VCN-01 in patients with refractory retinoblastoma. The Collaboration and License Agreement provides that if the trial results are positive and VCN is interested in continuing with the development of VCN-01 for the treatment of retinoblastoma; (a) the parties undertake to apply their best efforts to negotiate and, where appropriate, sign an agreement to collaborate in the development and execution of the following phases of the development of VCN-01 for the treatment of retinoblastoma; (b) the Institution shall grant to VCN an exclusive, worldwide and indefinite license to use and exploit the trial results and their possible patents exclusively for the treatment of retinoblastoma; (c) VCN shall pay the Foundation five hundred thousand Euros (€500,000), subject to reduction for any public and/or private economic aid that third parties may grant to the Institution for the conduct of the trial and/or any advance payments made by VCN before the end of the trial; (d) VCN shall pay the Foundation three hundred twenty thousand Euros (€320,000) once following the trial results of a pivotal study, to be carried out by VCN, has been completed which allows it to obtain the marketing authorization of the product following from the results, which payment must be made within a maximum period of four (4) years from the date on which Institution has delivered the final report of the trial to VCN; and (e) the parties will use their best efforts to negotiate and, where appropriate, sign a product supply agreement in order that the Hospital can use VCN-01 for compassionate use in the treatment of retinoblastoma. The Collaboration and License Agreement continues in force and effect until all obligations arising from the trial have been fulfilled, subject to early termination for a material breach by a party of any of their contractual and/or legal obligations, or, in the case of any other type of breach, when the breaching party has been asked in writing to remedy the breach and the breach is not cured within thirty (30) days from the date on which the written request was sent. Per the terms of the clinical trial agreement, the determination by the study Monitoring Committee that the study had a positive outcome means we will receive an exclusive, worldwide technology license, and related patents from Hospital Sant Joan de Déu for the treatment of pediatric patients with advanced retinoblastoma and we will pay to Hospital Sant Joan de Déu the amount of three hundred twenty thousand Euros (€320,265), or approximately $334,000, upon receipt by us of the final clinical study report.

On November 1, 2023, VCN and the Hospital entered into an agreement for an exclusive worldwide option to negotiate an exclusive license of certain Sant Joan de Deu intellectual property rights related to the use of VCN-01 in combination with topoisomerase I inhibitor chemotherapies for the treatment of cancer. This option was extended for an additional 12-months by an amendment signed in October, 2024 and again by an amendment signed January 2026. The collaboration builds on growing data that suggests coadministration of VCN-01 with topoisomerase I inhibitors such as topotecan can enhance VCN-01 replication and antitumor activity in preclinical cancer models. Combination of VCN-01 with a topoisomerase I inhibitor is expected to provide a synergistic antitumor effect wherein a chemotherapy-mediated increase in tumor VCN-01 levels may enable greater degradation of the tumor stroma, significantly increasing chemotherapy access and tumor destruction.

Washington University School of Medicine in St. Louis Clinical Trial Agreement

On August 7, 2019, we entered into a clinical trial agreement (the "CTA") with Washington University School of Medicine in St. Louis ("Washington University") to conduct a Phase 1b/2a single-center, randomized, double-blinded, placebo-controlled clinical trial designed to evaluate the safety, tolerability and pharmacokinetics of oral SYN-004 (ribaxamase) in up to 36 adult allogeneic hematopoietic cell transplant (HCT) recipients (the "Study"). Under the terms of the CTA, we will serve as the sponsor of the Study and supply SYN-004 (ribaxamase), as well as compensate Washington University for all research services to be provided in connection with the Study which is estimated to cost approximately $3,200,000. Dr. Erik R. Dubberke, Professor of Medicine and Clinical Director, Transplant Infectious Diseases at Washington University will serve as the principal investigator of the trial in collaboration with his Washington University colleague Dr. Mark A. Schroeder, Associate Professor of Medicine, Division of Oncology, Bone Marrow Transplantation and Leukemia.

The CTA continues in effect until completion of all obligations under the CTA. Either party may terminate the CTA prior to completion of its obligations (i) if authorization of the study is withdrawn by the FDA; (ii) if the emergence of any adverse reaction or side effect with SYN-004 (ribaxamase) administered in the Study is of such magnitude or incidence in the opinion of either party to support termination; or (iii) upon a breach of the terms of the CTA if the breaching party fails to cure the breach within 30 days after receipt of notice. We have the right to terminate the CTA (i) effective immediately if Washington University fails to perform the study in accordance with the terms of the protocol, the CTA or applicable laws or regulations or if Washington University or the principal investigator become debarred or (ii) upon 14 days written notice and Washington University has the right to terminate the CTA upon 14 days notice if the principal investigator becomes unable to perform or complete the Study and the parties have not, prior to the expiration of such fourteen (14) day period, agreed to an alternative principal investigator. Based upon our current available funding and our focus on our clinical development of VCN-01 we do not anticipate that enrollment for the third cohort will commence unless we obtain grant funding, or find a licensee or partner for the SYN-004 development program.

Rasayana License Agreement

On February 17, 2026, we entered into the Rasayana License Agreement with Rasayana, whereby we granted Rasayana an exclusive worldwide license with the right to grant sublicenses to research, develop, manufacture and commercialize any Product (as such term is defined in the Rasayana License Agreement), which includes SYN-020, comprising, containing, or covered by the Licensed IP (as such term is defined in the Rasayana License Agreement) and/or devised, developed, or produced using the Licensed IP. Under the terms and conditions of the Rasayana License Agreement, Rasayana has agreed to use commercially reasonable efforts to meet certain specified development milestones with respect to the Products. Additionally, pursuant to the terms of the Rasayana License Agreement, Rasayana will assume all responsibility and costs for the development and commercialization of the Products. Accordingly, going forward, we do not expect to continue to conduct research and development activities, including conducting further clinical studies, with respect to SYN-020, and do not expect to incur material expenditures in connection therewith.

As consideration for the license, on February 17, 2026, we received an upfront payment of $300,000 from Rasayana. In addition, we are entitled to receive from Rasayana development milestone payments of up to an aggregate of $16.0 million and sales milestone payments of up to an aggregate of $22.0 million upon achievement of certain development and net sales milestones with respect to Products. In addition, during the Royalty Term (as such term is defined in the Rasayana License Agreement), we are entitled to receive tiered royalties ranging from low to mid single digits on net sales of a Product. We will also be entitled to receive a certain percentage of any Sublicense Revenue (as such term is defined in the Rasayana License Agreement) received by Rasayana or its affiliates.

The term of the Rasayana License Agreement commenced on February 17, 2026 and continues on a country-by-country basis until the expiration of the Royalty Term. If either we or Rasayana materially breaches any material obligation under the Rasayana License Agreement and does not cure such breach, the non-breaching party may terminate the Rasayana License Agreement in its entirety; provided that if such breach is capable of being cured but cannot be cured within such sixty (60) day period and the breaching party initiates actions to cure such breach within such period and thereafter diligently pursues such actions, the breaching party shall have one additional period of sixty (60) days to cure such breach. Either party may also terminate the Rasayana License Agreement, upon written notice, if the other party has an Insolvency Event (as such term is defined in the Agreement). Rasayana has the right to terminate the Rasayana License Agreement for any or no reason upon ninety (90) days' written notice to us, including but not limited to instances in which the outcome of a clinical trial is adverse and/or unsatisfactory to Rasayana (in its reasonable discretion). If Rasayana suspends all material development efforts with respect to all Products for a period of one hundred and eighty (180) days, or fails to use commercially reasonable efforts to achieve any of the development milestones by the applicable deadline), then the Company may terminate the Rasayana License Agreement upon ninety (90) days prior written notice to Rasayana, unless Rasayana resumes material development

efforts within such period. Upon a termination, the rights granted under the Rasayana License Agreement terminate and revert irrevocably to the Company.

Manufacturing

VCN-01 (zabilugene almadenorepvec), VCN-11 and VCN - 12

Our OV platform viruses (e.g. VCN-01, VCN-11, and VCN - 12) are biologics that can be readily synthesized by processes that we have developed in collaboration with Contract and Development Manufacturing Organizations (CDMOs) such as Thermo Fisher, BioReliance, Recipharm Advanced Bio, Fujifilm Diosynth and others. We do not own or operate manufacturing facilities for the production of our product candidates, but we do produce and test viruses and virus processes at our facilities in Spain. Our cell and virus seed stocks and master/working cell banks are used for current and future production. Our cells for manufacturing are approved by and licensed from US regulatory authorities. Clinical and commercial supplies will be manufactured in facilities and by processes that comply with the FDA and other regulatory agency requirements. We plan to rely on third parties to manufacture commercial quantities of products that we successfully develop through regulatory approval. We have contracted with CDMOs to provide what we believe are adequate clinical supplies for our planned clinical trials.

Our upstream and downstream processes for producing oncolytic viruses are well understood in the industry and use industry standard cell factories and single use bioreactors for manufacturing. All downstream purifications employ single-use columns and filters, and release testing is performed by third-party vendors using qualified or validated assays. Critical quality attributes and other product testing specifications for our clinical supplies are agreed to with regulatory authorities prior to release and use.

We previously encountered some delays in manufacturing due to the impact of COVID-19 on the supply chain. The potential impact of similar supply chain issues from a future pandemic or other disruption to global trade and supply chains, if any, on our on-going and future clinical trials is currently unknown.

SYN-004 (ribaxamase) and SYN-020

Our product candidates SYN-004 and SYN-020 are biologics that can be readily synthesized by processes that we have developed; however, the manufacturing for our product candidates, including SYN-004 and SYN-020 may require long lead times and was previously subject to COVID-19 related global supply chain interruptions. We do not own or operate manufacturing facilities for the production of these product candidates for preclinical and clinical activities. We rely on third-party contract manufacturers, and in most cases only one third-party, to manufacture critical raw materials, drug substance and final drug product for our research, preclinical development and clinical trial activities. Commercial quantities of any drugs we seek to develop will have to be manufactured in facilities and by processes that comply with the FDA and other regulations, and we plan to rely on third parties to manufacture commercial quantities of products we successfully develop through FDA approval.

Pursuant to the Rasayana License Agreement, commencing February 17, 2026, Rasayana is now responsible for the manufacture of SYN-020, including the sourcing, receipt, storage and processing of raw materials; the manufacture, processing, testing, packing, re-packing, holding and shipment of in-process or finished product; and all costs associated with the foregoing.

Research and Development

During the years ended December 31, 2025 and 2024, we incurred approximately $8.6 million and $12.0 million, respectively, in research and development expenses.

Government Regulation

In the U.S., the formulation, manufacturing, packaging, storing, labeling, promotion, advertising, distribution and sale of our products are subject to regulation by various governmental agencies, including primarily the FDA. Our proposed activities may also be regulated by various agencies of the states, localities and foreign countries in which our proposed products may be manufactured, distributed and sold. The FDA, in particular, regulates the formulation, manufacture and labeling of prescription drugs, such as those that we intend to distribute. FDA regulations require us and our suppliers to meet relevant cGMP regulations for the preparation, packing, labeling, and storage of all drugs.

Any products manufactured or distributed by us pursuant to FDA approvals are subject to pervasive and continuing FDA regulation, including record-keeping requirements, reporting of adverse experiences, submitting periodic reports, drug sampling and distribution requirements, manufacturing or labeling changes, record-keeping requirements, and compliance with FDA promotion and advertising requirements. Drug manufacturers and their subcontractors are required to register their facilities with the FDA and state agencies, and are subject to periodic unannounced inspections for GMP compliance, imposing procedural and documentation requirements upon us and third-party manufacturers. Failure to comply with these regulations could result, among other things, in suspension of regulatory approval, recalls, suspension of production or injunctions, seizures, or civil or criminal sanctions. We cannot be certain that we or our present or future subcontractors will be able to comply with these regulations.

The FDA regulates prescription drug labeling and promotion activities in the United States. The FDA actively enforces regulations prohibiting the marketing of products for unapproved uses. The FDA permits the promotion of drugs for unapproved uses in certain circumstances, subject to stringent requirements. We and our product candidates are subject to a variety of state laws and regulations which may hinder our ability to market our products. Whether or not FDA approval has been obtained, approval by foreign regulatory authorities must be obtained prior to commencing clinical trials, and sales and marketing efforts in those countries. These approval procedures vary in complexity from country to country, and the processes may be longer or shorter than that required for FDA approval. We expect to incur significant costs to comply with these laws and regulations now or in the future.

The FDA, comparable foreign regulators and state and local pharmaceutical regulators impose substantial requirements upon clinical development, manufacture and marketing of pharmaceutical products. These and other entities regulate research and development and the testing, manufacture, quality control, safety, effectiveness, labeling, storage, record keeping, approval, advertising, and promotion of our products. The drug approval process required by the FDA under the Food, Drug, and Cosmetic Act (the "FDCA") and Public Health Service Act (the "PHS Act") (for biologics) generally involves:

- preclinical laboratory and animal tests;
- submission of an IND, prior to commencing human clinical trials;
- adequate and well-controlled human clinical trials to establish safety and efficacy for intended use;
- submission to the FDA of a new drug application ("NDA") or BLA; and
- FDA review and approval of an NDA or BLA.

The testing and approval process requires substantial time, effort, and financial resources, and we cannot be certain that any approval will be granted on a timely basis, if at all. OVs such as VCN-01 are genetically modified organisms and their import and use are subject to additional review and approval by dedicated agencies in some countries where we propose to run clinical trials, including Spain and other European countries.

Preclinical tests include laboratory evaluation of the product candidate, its chemistry, formulation and stability, and animal studies to assess potential safety and efficacy. Certain preclinical tests must be conducted in compliance with good laboratory practice regulations. Violations of these regulations can, in some cases, lead to invalidation of the studies, requiring them to be replicated. In some cases, long-term preclinical studies are conducted concurrently with clinical studies.

We will submit the preclinical test results, together with manufacturing information and analytical data, to the FDA as part of an IND, which must become effective before we begin human clinical trials. The IND automatically becomes effective 30 days after filing, unless the FDA raises questions about conduct of the trials outlined in the IND and imposes a clinical hold, in which case, the IND sponsor and FDA must resolve the matters before clinical trials can begin. It is possible that our submissions may not result in FDA authorization to commence clinical trials. The timing and requirements of IND review may differ from the FDA in other countries, potentially delaying study initiation at sites in those countries.

Clinical trials must be supervised by qualified investigators in accordance with current good clinical practice ("cGCP") regulations, which include informed consent requirements. Each study must be approved and monitored by the appropriate Institutional Review Boards ("IRBs") or Institutional Ethics Committees ("IECs") which are periodically informed of the study's progress, adverse events and changes in research. OVs such as VCN-01 are genetically modified organisms and their use is also subject to review and approval by the Institutional Biosafety Committee ("IBC") at each clinical trial site. Annual updates are submitted to the FDA and comparable foreign regulators (if required) with more frequent reporting if certain serious adverse events occur.

Human clinical trials of drug candidates typically have three sequential phases that may overlap:

Phase 1: The drug is initially tested in healthy human subjects or patients for safety, dosage tolerance, absorption, metabolism, distribution, and excretion.

Phase 2: The drug is studied in a limited patient population to identify possible adverse effects and safety risks, determine efficacy for specific diseases and establish dosage tolerance and optimal dosage.

Phase 3: When Phase 2 evaluations demonstrate that a dosage range is effective with an acceptable safety profile, Phase 3 trials to further evaluate dosage, clinical efficacy and safety, are undertaken in an expanded patient population, often at geographically dispersed sites.

We cannot be certain that we will successfully complete Phase 1, Phase 2, or Phase 3 testing of our product candidates within any specific time period, if at all. Furthermore, the FDA or comparable foreign regulator, an IRB/IEC or the IND sponsor may suspend clinical trials at any time on various grounds, including a finding that subjects or patients are exposed to unacceptable health risk. Under the Pediatric Research Equity Act, we also must prepare, within 60 days of an End of Phase 2 meeting, a pediatric study plan or request for waiver or deferral of pediatric studies in the indication under development. Concurrent with these trials and studies, we also develop chemistry and physical characteristics data and finalize a manufacturing process in accordance with cGMP requirements. The manufacturing process must conform to consistency and quality standards, and we must develop methods for testing the quality, purity, and potency of the final products. Appropriate packaging is selected and tested, and chemistry stability studies are conducted to demonstrate that the product does not undergo unacceptable deterioration over its shelf-life. Results of the foregoing are submitted to the FDA as part of an NDA (or BLA in case of biologic products) for marketing and commercial shipment approval. The FDA reviews each NDA or BLA submitted and may request additional information. A 60-day period after the sponsor's submission of an NDA or BLA is used by the FDA to determine whether the application is sufficiently complete to permit substantive review, in which case the application is accepted for filing. The timing and requirements of NDA or BLA review may differ from the FDA in other countries,

Once the FDA accepts the NDA or BLA for filing, it begins its in-depth review. The FDA has substantial discretion in the approval process and may disagree with our interpretation of the data submitted or identify new concerns. The process may be significantly extended by requests for new information or clarification of information already submitted. As part of this review, the FDA may refer the application to an advisory committee, typically a panel of clinicians. Manufacturing establishments are often inspected prior to NDA or BLA approval to assure compliance with GMPs and with manufacturing commitments made in the application.

Submission of an NDA or BLA with clinical data requires payment of a substantial fee. The FDA assigns a goal for review and decision on the application, in which the FDA may approve the NDA or BLA or issue a complete response letter outlining information needed to support approval, including a potential need for additional clinical data. Even if these data are submitted, the FDA may ultimately decide the NDA or BLA does not satisfy approval criteria. If the FDA approves the NDA or BLA, the product becomes available for marketing. Product approval may be withdrawn if regulatory compliance is not maintained or safety problems occur. The FDA may require post-marketing studies, also known as Phase 4 studies, as a condition of approval, and Risk Evaluation and Mitigation Strategies (REMS) requires surveillance programs to monitor approved products that have been commercialized. The agency has the power to require changes in labeling or prohibit further marketing based on the results of post-marketing surveillance.

Satisfaction of these and other regulatory requirements typically takes several years, and the actual time required may vary substantially based upon the type, complexity and novelty of the product. Government regulation may delay or prevent marketing of potential products for a considerable period of time and impose costly procedures on our activities. We cannot be certain that the FDA or other regulatory agencies will approve any of our product candidates on a timely basis, if at all. Success in preclinical or early-stage clinical trials does not assure success in later-stage clinical trials. Data obtained from preclinical and clinical activities are not always conclusive and may be susceptible to varying interpretations that could delay, limit or prevent regulatory approval. Even if a product receives regulatory approval, the approval may be significantly limited to specific indications or uses.

Even after regulatory approval is obtained, later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market. Significant delays in obtaining, or failures to obtain regulatory approvals would have a material adverse effect on our business.

The FDA or comparable foreign regulatory agency may change their policies, and additional government regulations may be enacted which could prevent or delay regulatory approval of our potential products. In 2025, in connection with the U.S. presidential transition and change in administration, there were significant changes in leadership at the FDA as well as FDA priorities. Increased attention to

the containment of health care costs worldwide could result in new government regulations materially adverse to our business. Public perception and sentiment regarding genetically modified organisms and/or viral therapies (including vaccines) can be highly variable and may impact legislation regarding the potential suitability of our products. We cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the U.S. or abroad.

Orphan Drug Act

Under the Orphan Drug Act, as amended by the FDA Reauthorization Act of 2017, the FDA may grant orphan designation to a drug or biologic 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 more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for this type of disease or condition will be recovered from sales in the United States for that drug. Orphan Drug designation must be requested before submitting an NDA or BLA. After the FDA grants orphan drug designation, the name of the sponsor, identity of the drug or biologic and its potential orphan use are disclosed publicly by the FDA. The orphan drug designation does not shorten the duration of the regulatory review or approval process, but does provide certain advantages, such as a waiver of Prescription Drug User Fee Act ("PDUFA") fees, enhanced access to FDA staff and potential waiver of pediatric research requirements.

If a product that has orphan drug designation subsequently receives the first FDA approval for the disease 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, including a full NDA, to market the same drug or biologic for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. Orphan drug exclusivity does not prevent FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the application user fee. A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. In addition, exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

In February 2022, the FDA granted orphan drug designation to VCN - 01 for the treatment of retinoblastoma, and in June 2023, the FDA granted Orphan Drug designation to VCN - 01 for the treatment of pancreatic cancer.

Accelerated Approval

There are a variety of pathways under which applicants may seek expedited approval from the FDA, including Fast Track, breakthrough therapy, priority review and accelerated approval. Fast Track is a process designed to facilitate the development and expedite the review of investigational drugs to treat serious conditions and that fill an unmet medical need. Drugs that receive Fast Track designation may be eligible for more frequent communications and meetings with the FDA to discuss the drug's development plan, including the design of the proposed clinical trials, use of biomarkers and the extent of data needed to support approval. Drugs with Fast Track designation may also qualify for accelerated approval and priority review of new drug applications if relevant criteria are met. However, Fast Track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

The FDA may designate a product for priority review if it is a product that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. The FDA determines, on a case-by-case basis, whether the proposed product represents a significant improvement when compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting product reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, and evidence of safety and effectiveness in a new subpopulation. Under priority review, the FDA reviews an application in six months rather than ten months after it is accepted for filing.

The FDA accelerated approval program provides for early approval of drugs based on a drug on a clinical trial(s) showing that the drug meets a surrogate or an intermediate clinical endpoint rather than a clinical benefit endpoint. Accelerated approval is possible for drugs for serious conditions that fill an unmet medical need.

A surrogate endpoint used for accelerated approval is a marker, such as a laboratory measurement, that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. Likewise, 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. Because it sometimes can take many years for a drug trial to show a clinical benefit, the use of a surrogate endpoint or an intermediate clinical endpoint can significantly shorten the time required to complete clinical trials and obtain FDA approval.

If a drug receives an accelerated approval, the company that sponsored the application must conduct a post-approval trial to confirm the anticipated clinical benefit. These trials are known as Phase 4 or post-approval confirmatory trials. If the confirmatory trial shows that the drug actually provides a clinical benefit, then the FDA grants traditional approval for the drug. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, will 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. If the confirmatory trial does not show that the drug provides clinical benefit, FDA has regulatory procedures in place that could lead to removing the drug from the market.

Rare Pediatric Disease Vouchers

The Rare Pediatric Disease Voucher Program is intended to encourage development of new drug and biological products for prevention and treatment of certain rare pediatric diseases. Although there are existing incentive programs to encourage the development and study of drugs and biologics for rare diseases, pediatric populations, and unmet medical needs, this program provides an additional incentive for the development of drugs and biologics for rare pediatric diseases, which may be used alone or in combination with other incentive programs. A rare pediatric disease is defined as a disease that is a serious or life-threatening disease in which the serious or life-threatening manifestations primarily affect individuals aged from birth to 18 years, including age groups often called neonates, infants, children, and adolescents; and is a rare disease or condition as defined in the FDCA, which includes diseases and conditions that affect fewer than 200,000 persons in the United States and diseases and conditions that affect a larger number of persons and for which there is no reasonable expectation that the costs of developing and making available the product in the United States can be recovered from sales of the product in the United States.

The sponsor of an application for a drug product that obtains rare pediatric disease designation may be eligible for a voucher that can be used or sold to obtain a priority review for a subsequent application submitted under section 505(b)(1) of the FDCA or section 351 of the PHS Act. A rare pediatric disease drug product must meet certain eligibility requirements for a priority voucher at the time the sponsor seeks approval. In February 2026, legislative authorization for the rare pediatric disease priority review voucher (PRV) program extended the program to enable award of PRVs for approved products until September 30, 2029.

If a BLA for VCN-01 (zabilugene almadenorepvec) for the treatment of retinoblastoma is approved by the FDA before the required deadline, we may be eligible to receive a priority review voucher.

Pediatric Information and Pediatric Exclusivity

Under the Pediatric Research Equity Act (“PREA”), certain NDAs and BLAs and certain supplements to an NDA or BLA must contain data to assess the safety and efficacy of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of pediatric data or full or partial waivers. The Food and Drug Administration Safety and Innovation Act (“FDASIA”), amended the FDCA to require that a sponsor who is planning to submit a marketing application for a drug that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration submit an initial Pediatric Study Plan (“PSP”) within 60 days of an end-of-Phase 2 meeting or, if there is no such meeting, as early as practicable before the initiation of the Phase 3 or Phase 2/3 study. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. The FDA and the sponsor must reach an agreement on the PSP. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from preclinical studies, early phase clinical trials and/or other clinical development programs.

The Best Pharmaceuticals for Children Act, (“BPCA”), provides NDA holders a six-month extension of any exclusivity — patent or non-patent — for a drug if certain conditions are met. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. Conditions for exclusivity include the FDA’s determination that information relating to the use of a new drug in the pediatric population may produce health benefits in that population, the FDA’s written request for pediatric studies, and the applicant’s agreeing to perform, and reporting on, the requested studies within the statutory timeframe. Applications under the BPCA are treated as priority applications, with all of the benefits that designation confers.

Drug Development in the European Union

Orphan Drug Designation is also available in Europe from the European Medicines Agency (EMA) and provides for 10 years of market exclusivity if granted. The requirements, costs and timing for obtaining and maintaining EMA Orphan Drug Designation differ from the FDA.

In May 2011, the "COMP" from the EMA recommended granting Orphan Medicinal Product Designation to VCN-01 for the treatment of pancreatic cancer and in June 2011, the EC confirmed the designation under Regulation ("EC") No 141/2000 of the European Parliament and of the Council.

In October 2024, the EC adopted EMA recommendation to grant Orphan Medicinal Product Designation to VCN-01 for the treatment of retinoblastoma. The European Commission confirmed the designation under Regulation No 141/2000 of the European Parliament and of the Council.

In the European Union, our future products may also be subject to extensive regulatory requirements. Similar to the United States, the marketing of medicinal products is subject to the granting of marketing authorizations by regulatory agencies. Also, as in the United States, the various phases of pre-clinical and clinical research in the European Union are subject to significant regulatory controls.

In the European Union, approval of new medicinal products can be obtained through one of three processes: the mutual recognition procedure, the centralized procedure and the decentralized procedure. We intend to determine which process we will follow, if any, in the future.

Mutual Recognition Procedure: An applicant submits an application in one European Union member state, known as the reference member state. Once the reference member state has granted the marketing authorization, the applicant may choose to submit applications in other concerned member states, requesting them to mutually recognize the marketing authorizations already granted. Under this mutual recognition process, authorities in other concerned member states have 55 days to raise objections, which must then be resolved by discussion among the concerned member states, the reference member state and the applicant within 90 days of the commencement of the mutual recognition procedure. If any disagreement remains, all considerations by authorities in the concerned member states are suspended and the disagreement is resolved through an arbitration process. The mutual recognition procedure results in separate national marketing authorizations in the reference member state.

Centralized Procedure: This procedure is currently mandatory for products developed by means of a biotechnological process and optional for new active substances and other "innovative medicinal products with novel characteristics." Under this procedure, an application is submitted to the European Agency for the Evaluation of Medical Products. Two European Union member states are appointed to conduct an initial evaluation of each application. These countries each prepare an assessment report that is then used as the basis of a scientific opinion of the Committee on Proprietary Medical Products. If this opinion is favorable, it is sent to the European Commission, which drafts a decision. After consulting with the member states, the European Commission adopts a decision and grants a marketing authorization, which is valid throughout the European Union and confers the same rights and obligations in each of the member states as a marketing authorization granted by that member state.

Decentralized Procedure: The most recently introduced of the three processes for obtaining approval of new medicinal processes in the European Union, the decentralized procedure is similar to the mutual recognition procedure described above, but with differences in the timing that key documents are provided to concerned member states by the reference member state, the overall timing of the procedure and the possibility of, among other things, "clock stops" during the procedure.

Post-Marketing Requirements

Following approval of a new product, a pharmaceutical company and the approved product are subject to continuing regulation by the FDA and other regulatory authorities, including, among other things, monitoring and recordkeeping activities, reporting to applicable regulatory authorities of adverse experiences with the product, providing the regulatory authorities with updated safety and efficacy information, product sampling and distribution requirements, and complying with promotion and advertising requirements, which include, among others, standards for direct-to-consumer advertising, restrictions on promoting drugs for uses or in patient populations not described in the drug's approved labeling (known as "off-label use"), and limitations on industry-sponsored scientific and educational activities. Although physicians may prescribe legally available drugs for off-label uses, drugs may be marketed only for the approved indications and in accordance with the provisions of the approved labeling. Modifications or enhancements to the products or labeling or changes of site of manufacture are often subject to the approval of the FDA and other regulators, which may or may not be

received or may result in a lengthy review process. The FDA regulations require the products be manufactured in specific approved facilities and in accordance with current good manufacturing practices, and NDA holders must list their products and register their manufacturing establishments with the FDA. These regulations also impose certain organizational, procedural and documentation requirements with respect to manufacturing and quality assurance activities. Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with current good manufacturing practice and other laws. NDA holders using contract manufacturers, laboratories or packagers are responsible for the selection and monitoring of qualified firms. These firms are subject to inspections by the FDA at any time, and the discovery of violative conditions could result in enforcement actions that interrupt the operation of any such facilities or the ability to distribute products manufactured, processed or tested by them.

Pricing and Reimbursement

In both the U.S. and foreign markets, the ability to successfully commercialize product candidates that have obtained regulatory approval by the FDA or other governmental authorities depends in significant part on the availability of adequate financial coverage and reimbursement from third party payors, including, in the U.S., governmental payors such as Medicare and Medicaid, managed care organizations, and private commercial health insurers. There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, the principal decisions about reimbursement for new products are typically made by the Centers for Medicare & Medicaid Services ("CMS"). Private payors tend to follow CMS to a substantial degree. However, no uniform or consistent policy of coverage and reimbursement for drug products exists among third-party payors. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor as well as from state to state. Consequently, the coverage determination process is often a time-consuming and costly process that must be played out across many jurisdictions and different entities. Further, a payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved.

In addition, direct or indirect governmental price regulation may affect the prices that we may charge for product candidates. For example, in the United States and some foreign jurisdictions, the prices of pharmaceutical products are subject to direct price controls (by law) and to drug reimbursement programs with varying price control mechanisms. There have been, and we expect there will continue to be, legislative and regulatory proposals to change the healthcare system in ways that could significantly affect the pharmaceutical industry, including the Patient Protection and Affordable Care Act of 2010 and the Inflation Reduction Act of 2022. We anticipate that in the U.S., Congress, state legislatures, and private sector entities will continue to consider and may adopt healthcare policies intended to curb rising healthcare costs.

Other Healthcare Laws and Compliance Requirements

In the United States, the research, manufacturing, distribution, sale and promotion of drug products and medical devices are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including the U.S. Department of Justice, state Attorneys General, and other state and local government agencies. The federal Anti-Kickback Statute prohibits any person, including a prescription drug manufacturer (or a party acting on its behalf), from knowingly and willfully soliciting, receiving, offering or providing remuneration, directly or indirectly, to induce or reward 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 federal False Claims Act ("FCA") imposes liability on any person or entity that, among other things, knowingly presents or causes to be presented, a false or fraudulent claim for payment by a federal healthcare program. The qui tam provisions of the FCA allow a private individual to bring civil actions on behalf of the federal government alleging that the defendant has submitted a false claim to the federal government, and to share in any monetary recovery. In addition, various states have enacted anti-kickback statues and false claims laws analogous to the FCA The Federal Physician Payments Sunshine Act within the Affordable Care Act, or the ACA, and its implementing regulations, require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report on an annual basis information related to certain payments or other transfers of value made or distributed to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals and certain ownership and investment interests held by physicians and their immediate family members, with the information made publicly available on a searchable website Also, the Health Insurance Portability and Accountability Act of 1996 (HIPAA)), as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH) and its implementing regulations, imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to "business associates" — independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties

directly applicable to business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions.

Because of the breadth of these and other laws and the narrowness of available statutory and regulatory exemptions, it is possible that some of our business activities could be subject to challenge under one or more of such laws. If our operations are found to be in violation of any of the federal and state laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including criminal and significant civil monetary penalties, damages, fines, imprisonment, exclusion from participation in government healthcare programs, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of pre-marketing product approvals, private "qui tam" actions brought by individual whistleblowers in the name of the government or refusal to allow us to enter into supply contracts, including government contracts, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

In order to market any product outside of the United States, a company also must comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, use of genetically modified organisms, marketing authorization, commercial sales and distribution of products. Whether or not it obtains FDA approval for a product, an applicant will need to obtain the necessary approvals by the comparable foreign regulatory authorities before it can initiate clinical trials or market products in those countries or jurisdictions. Specifically, the process governing approval of medicinal products in the EU generally follows the same lines as in the United States. It entails satisfactory completion of pharmaceutical development, nonclinical studies and adequate and well-controlled clinical trials to establish the safety and efficacy of the medicinal product for each proposed indication. It also requires the submission to relevant competent authorities for clinical trials authorization and to the EMA or to competent authorities in EU Member States for a marketing authorization application, or MAA, and granting of a marketing authorization by competent authorities in EU Member States or the European Commission before the product can be marketed and sold in the EU.

Data Privacy

Strict data privacy laws regulating the collection, transmission, storage and use of employee data and consumers' personally-identifying information are evolving in the European Union, U.S. and other jurisdictions in which we operate. Outside of the United States, the laws, regulations and standards in many jurisdictions apply broadly to the collection, use, and other processing of personal information. For example, in the European Union, the collection and use of personal data are governed by the provisions of the General Data Protection Regulation (the "GDPR"). The GDPR, together with national legislation, regulations and guidelines of the European Union. member states governing the processing of personal data, impose strict obligations on entities subject to the GDPR, including but not limited to: (i) accountability and transparency requirements, and enhanced requirements for obtaining valid consent from data subjects; (ii) obligations to consider data protection as any new products or services are developed and to limit the amount of personal data processed; (iii) obligations to comply with the data protection rights of data subjects; and (iv) obligations to report certain personal data breaches to governmental authorities and individuals. Data protection authorities from the different E.U. member states and other European countries may enforce the GDPR and national data protection laws differently, and introduce additional national regulations and guidelines, which adds to the complexity of processing European personal data. Failure to comply with the requirements of the GDPR and the related national data protection laws may result in significant monetary fines and other administrative penalties (the GDPR authorizes fines for certain violations of up to 4% of global annual revenue or €20 million, whichever is greater) as well as civil liability claims from individuals whose personal data was processed. Additionally, expenses associated with compliance could reduce our operating margins.

The GDPR also prohibits the transfer of personal data from the E.U. to countries outside of the E.U. unless made to a country deemed by the European Commission to provide adequate protection for personal data or accomplished by means of an approved data transfer mechanism (e.g., standard contractual clauses). Data protection authority guidance and enforcement actions that restrict companies' ability to transfer data may increase risk relating to data transfers or make it more difficult or impossible to transfer E.U. personal data to the U.S.

Environmental, Health, and Safety Regulation

We are subject to numerous federal, state and local environmental, health and safety ("EHS"), laws and regulations relating to, among other matters, safe working conditions, product stewardship, environmental protection, and handling or disposition of products, including those governing the generation, storage, handling, use, transportation, release, and disposal of hazardous or potentially hazardous materials, medical waste, and infectious materials that may be handled by our research laboratories. Some of these laws and

regulations also require us to obtain licenses or permits to conduct our operations. If we fail to comply with such laws or obtain and comply with the applicable permits, we could face substantial fines or possible revocation of our permits or limitations on our ability to conduct our operations. Certain of our development activities involve use of hazardous materials, and we believe we are in compliance with the applicable environmental laws, regulations, permits, and licenses. However, we cannot ensure EHS liabilities will not develop in the future. EHS laws and regulations are complex, change frequently and have tended to become more stringent over time. Although the costs to comply with applicable laws and regulations, have not been material, we cannot predict the impact on our business of new or amended laws or regulations or any changes in the way existing and future laws and regulations are interpreted or enforced, nor can we ensure we will be able to obtain or maintain any required licenses or permits.

Competitive Environment

The pharmaceutical and biotechnology industries are characterized by rapidly evolving technology and intense competition. Our competitors include major multi-national pharmaceutical companies and biotechnology companies developing both generic and proprietary therapies to treat serious diseases. Many of these companies are well-established and possess technical, human, research and development, financial, and sales and marketing resources significantly greater than ours. In addition, many of our potential competitors have formed strategic collaborations, partnerships and other types of joint ventures with larger, well established industry competitors that afford these companies potential research and development and commercialization advantages in the therapeutic areas we are currently pursuing.

Academic research centers, governmental agencies and other public and private research organizations are also conducting and financing research activities which may produce products directly competitive to those being developed by us. In addition, many of these competitors may be able to obtain patent protection, obtain FDA and other regulatory approvals and begin commercial sales of their products before us.

Our oncology product candidates compete with all other oncology products being developed by third parties for our target indications.

Only three OV products have been approved in different global markets. Amgen Inc.'s Imlygic® (T-VEC, OncoVEX) for melanoma (USA); Daiichi Sankyo Company, Limited's DELYTACT® for malignant glioma (Japan) and Shanghai Sunway Biotech Co., Ltd Oncorine® for patients with late-stage refractory nasopharyngeal cancer (China). A BLA resubmission by Replimune, Inc. for their OV RP1 (vusolimogene oderparepvec) in combination with nivolumab for patients with advanced melanoma has been accepted by the FDA with a Prescription Drug User Fee Act (PDUFA) action date of April 10, 2026. In June 2024, CG Oncology, Inc. announced that their Phase 3 OV cretostimogene grenadenorepvec was available in the U.S. for patients with BCG-unresponsive non-muscle invasive bladder cancer ("NMIBC") who meet certain program eligibility criteria. On November 14, 2025, CG Oncology reported initiation of a rolling BLA submission to the FDA for cretostimogene monotherapy in high-risk (HR) BCG-unresponsive non-muscle invasive bladder cancer (NMIBC), with completion of the BLA submission in 2026.

More than 60 companies have publicly identified that they are pursuing clinical development of different forms of OV products. Adenoviruses are the most commonly used viruses in these programs, with modified adenoviruses under development by companies including AdCure Bio LLC, Calidi Biotherapeutics, Inc., Candel Therapeutics, Inc., CG Oncology, Inc., Elicera Therapeutics AB, EpicentRx, Inc., GeneMedicine, Co Ltd., Inc., Lokon Pharma AB, Memgen, Inc., NewGenPharm Incorporation, Oncolys BioPharma, Inc., Orca Therapeutics B.V., Akamis Bio Ltd (formerly PsiOxus Therapeutics Ltd), Shanghai Sunway Biotech Co., Ltd, Theolytics Ltd, TILT Biotherapeutics, Ltd., UroGen Pharma, and Valo Therapeutics Oy.

OV products have been or are being developed using other virus backbones, including: arenavirus (Hookipa Pharma, Inc.), Coxsackie virus (Viralytics Ltd., Oncorus Inc.); herpes simplex virus (Amgen, Inc., Candel Therapeutics, Inc., Daiichi Sankyo Company Ltd.,ImmVira Co. Ltd, Replimune, Inc., Takara Bio, Inc., Treovir LLC, Virogin Biotech, Inc. Wuhan Binhui Biotechnology Co., Ltd.); Maraba virus (Turnstone Biologics, Inc.); measles virus (Themis Biosciences GmbH, Vyriad, Inc.); myxoma virus (OncoMyx Therapeutics, Inc.); parvovirus (Oryx GmbH & Co. KG), reovirus (Oncolytics Biotech, Inc.); poliovirus (Istari Oncology, Inc.);Seneca Valley virus (Seneca Therapeutics Inc., Oncorus Inc.); vesicular stomatitis virus (Boehringer Ingelheim, Cytonus Therapeutics, Inc., Vyriad, Inc.); and vaccinia viruses (Genelux Corporation, Imugene Ltd, Joint Biosciences Ltd, KaliVir Immunotherapeutics LLC, SillaJen, Inc., Transgene SA, Turnstone Biologics, Corp.).

OV companies that have identified pancreatic cancer or PDAC as a proposed clinical indication include Akamis Bio Ltd, Boehringer Ingelheim GmbH, Candel Therapeutics, Inc., GeneMedicine, Co Ltd., Lokon Pharma AB, Memgen, Inc., NewGenPharm Incorporation, Oncolytics Biotech, Oryx GmbH & Co. KG, Takara Bio, Inc., TILT Biotherapeutics Ltd), V2ACT Therapeutics™ LLC (a Genelux

Corporation joint venture), Virogin Biotech, Inc.,and Wuhan Binhui Biotechnology Co., Ltd. OV companies that have identified retinoblastoma as a potential target indication include Seneca Therapeutics Inc. and Shanghai Sunway Biotech Co., Ltd.

Theriva Biologics' OV products are designed to be systemically, intratumorally or intravitreally injected; selectively replicate only in tumor cells versus normal host cells; have reduced liver tropism compared to wild type adenovirus type 5; and express an enzyme (PH20 hyaluronidase) that degrades the tumor stroma barrier. If confirmed in Phase 2 and later clinical trials, we believe these features significantly differentiate Theriva Biologics' products from competing OVs and will enable our products to be co-administered with other therapeutic modalities such as chemotherapy and immuno - oncology products to improve cancer treatment outcomes.

Companies that currently sell or are developing proprietary products for the prevention and treatment of *C. difficile* infection include: Actelion Pharmaceutical Ltd., Artugen Therapeutics, Inc., Acurx Pharmaceuticals, Inc., Deinove, Pfizer Inc., Merck & Co. Inc., Merus B.V., Pfizer Inc., Rebiotix, Inc., Seres Therapeutics, Inc., Summit Therapeutics plc. and Vedanta Biosciences Inc. Companies that sell or are developing products for the treatment or prevention of acute graft - versus - host - disease (aGVHD) include: Amgen, Inc., Astellas Pharma, Janssen Biotech, Inc., Mallinckrodt plc, Mesoblast, Inc., Novartis International AG, Pfizer, Inc. Roche AG and Takeda Pharmaceutical Company Ltd.

Not only do our product candidates compete with other product candidates being developed for similar or the same indications, we also compete for employees, clinical trial sites, and clinical trial participants.

Corporate History

Our predecessor, Sheffield Pharmaceuticals, Inc., was incorporated in 1986, and in 2006 engaged in a reverse merger with Pipex Therapeutics, Inc., a publicly-traded Delaware corporation formed in 2001. After the reverse merger, we changed our name to Pipex Pharmaceuticals, Inc., and in October 2008 we changed our name to Adeona Pharmaceuticals, Inc. On October 15, 2009, we engaged in a merger with a wholly owned subsidiary for the purpose of reincorporating in the State of Nevada. On February 15, 2012, we changed our name to Synthetic Biologics, Inc. On August 10, 2018, we effected a one for thirty-five reverse stock split of our authorized, issued and outstanding Common Stock. On July 15, 2022, we effected a one for ten reverse stock split of our authorized, issued and outstanding Common Stock. On October 12, 2022, we changed our name to Theriva Biologics, Inc. Effective November 15, 2022, as part of our corporate rebranding, our subsidiary VCN changed its name to Theriva Biologics S.L. without other changes to its corporate structure. On August 26, 2024, we effected a one for twenty-five reverse stock split of our authorized, issued and outstanding Common Stock.

Human Capital

We believe that our success depends upon our ability to attract, develop and retain key personnel. As of March 12, 2026, we employed 16 individuals, all but one of whom are full-time employees. Ten (10) were part of VCN's research and clinical development team located in Spain, Two (2) are part of VCN's management team located in Spain and Four (4) (including the CEO) are part of our corporate development, financial reporting and accounting teams located in the United States.

A significant number of our management and professional employees have had prior experience with pharmaceutical, biotechnology or medical product companies. None of our employees in the United States are covered by collective bargaining agreements, and management considers relations with our employees to be in good standing. As is the usual situation in Spain, all the employees are currently covered by a collective bargaining system specific for the pharma sector. Management believes that it has sufficient human capital to operate its business successfully.

On September 28, 2025, our Board of Directors approved a plan to resize and restructure the company for purposes of focusing our attention on business development and licensing activities, clinical trial planning, exploratory VCN-01 manufacturing scale-up, limited preclinical activities related to VCN-01 and VCN-12 (the first candidate from our VCN-X discovery program), and interactions with the FDA and the EMA for proposed pivotal clinical trials of VCN-01 in patients with mPDAC and retinoblastoma (the "Plan"). Pursuant to the Plan, on September 30, 2025, we implemented a workforce reduction of seven employees or 32% of our then global workforce. The goal of this reduction was to direct our resources towards the activities detailed above in the Plan, which we believe will represent its best opportunity for success. We completed the employee reduction immediately and incurred a total of approximately $520,000 in charges in connection with the workforce reduction, which was accrued for as of September 30, 2025. These charges consist primarily of cash severance and benefits over a three-month period, in connection with the workforce reduction. The Plan is expected to save approximately $1.8 million in compensation and benefits annually, and together with additional anticipated operating cost reductions and capital raised pursuant to the ATM Sales Agreement, we expect that it will extend our cash runway into the first quarter of 2027;

however, the current cash will only be sufficient to run certain clinical trials and no assurances can be provided and our cash could differ materially from our expectations based on various factors, many of which are out of our control.

Competitive Pay and Benefits

Our compensation programs are designed to align the compensation of our employees with our performance and to provide the proper incentives to attract, retain and motivate employees to achieve superior results. The structure of our compensation programs balances incentive earnings for both short-term and long-term performance. Specifically:

- we provide employee wages that are competitive and consistent with employee positions, skill levels, experience, knowledge and geographic location;
- we engage nationally recognized outside compensation and benefits consulting firms to independently evaluate the effectiveness of our executive compensation and benefit programs and to provide benchmarking against our peers within the industry;
- we align our executives' long-term equity compensation with our shareholders' interests by linking realizable pay with stock performance; and
- all employees are eligible for health insurance, paid and unpaid leaves, a retirement plan and life and disability/accident coverage. We also offer a variety of voluntary benefits that allow employees to select the options that meet their needs, including flexible time-off, telemedicine, and unpaid parental leave.

Available Information

Additional information about Theriva Biologics is contained on our website, *www.therivabio.com*. Information contained on our website is not incorporated by reference into, and does not form any part of, this Annual Report. We have included our website address as a factual reference and do not intend it to be an active link to our website. Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act are available free of charge through the investor relations page of our internet website as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission (the "SEC"). The following Corporate Governance documents are also posted on our website: Code of Conduct, Code of Ethics for Financial Management and the Charters for the Audit Committee, Compensation Committee and Nominations Committee of the Board of Directors. Our phone number is (301) 417-4364 and our facsimile number is (301) 417-4367. The SEC maintains an internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the Commission. The address of that website is *www.sec.gov.*

Item 1A. Risk Factors.

Investing in our securities involves a high degree of risk. In addition to the risks related to our business set forth in this Annual Report and the other information included in this Annual Report, you should carefully consider the risks described below before purchasing our securities. Additional risks, uncertainties and other factors not presently known to us or that we currently deem immaterial may also impair our business operations.

The risks and uncertainties described below are not the only ones we face. Our business, financial condition and operating results can be affected by a number of factors, whether currently known or unknown, including but not limited to those described below. Any one or more of such factors could directly or indirectly cause our actual results of operations and financial condition to vary materially from past or anticipated future results of operations and financial condition. Any of these factors, in whole or in part, could materially and adversely affect our business, financial condition, results of operations and stock price. References to past events are provided by way of example only and are not intended to be a complete listing or a representation as to whether or not such factors have occurred in the past or their likelihood of occurring in the future.

Because of the following factors, as well as other factors affecting our financial condition and operating results, past financial performance should not be considered to be a reliable indicator of future performance, and investors should not use historical trends to anticipate results or trends in future periods.

RISKS RELATED TO OUR FINANCIAL POSITION AND CAPITAL REQUIREMENTS

Our auditor's report on our consolidated financial statements contains an explanatory paragraph regarding our ability to continue as a going concern.

Our consolidated financial statements as of December 31, 2025 have been prepared under the assumption that we will continue as a going concern for the next twelve months. In addition, our independent registered public accounting firm has issued a report that includes an explanatory paragraph referring to our recurring losses from operations (anticipated continued losses in the future) and net capital deficiency that raise substantial doubt in our ability to continue as a going concern without additional capital becoming available. Our ability to continue as a going concern is dependent upon our ability to obtain additional equity or debt financing, attain further operating efficiencies, reduce expenditures, and, ultimately, to generate revenue. Our consolidated financial statements as of December 31, 2025 did not include any adjustments that might result from the outcome of this uncertainty. We expect that our current cash will be able to fund operations into the first quarter of 2027; however, the current cash will only be sufficient to run certain clinical trials and no assurances can be provided and our cash could differ materially from our expectations based on various factors, many of which are out of our control.

We will need to raise additional capital to operate our business and our failure to obtain funding when needed may force us to delay, reduce or eliminate certain of our development programs or commercialization efforts.

During the year ended December 31, 2025, our operating activities used net cash of approximately $16.7 million and as of December 31, 2025 our cash and cash equivalents were $13.1 million. With the exception of the three months ended December 31, 2017 and June 30, 2010, we have experienced significant losses since inception and have a significant accumulated deficit. As of December 31, 2025, our accumulated deficit totaled approximately $358.7 million on a consolidated basis. Pursuant to the Purchase Agreement entered into in connection with the Acquisition, we have agreed to use reasonable efforts to commercialize VCN-01. Additionally, pursuant to the Purchase Agreement, we are required to pay up to $70.2 million in contingent consideration upon the achievement of certain milestones, including regulatory filings, of which to date $7.3 million has been paid and an additional $5.0 million has been earned but deferred pending ongoing discussion with Grifols. If we are required to make the deferred $5.0 million milestone payment to Grifols, it will significantly deplete our cash and cash equivalents, which could materially and adversely affect our liquidity and limit our ability to fund operations or meet other financial obligations. We expect to incur additional operating losses in the future and therefore expect our cumulative losses to increase. With the exception of the quarter ended June 30, 2010, and limited laboratory revenues from Adeona Clinical Laboratory, which we sold in March 2012, we have generated very minimal revenues. We do not expect to derive revenue from any source in the near future until we or our potential partners successfully commercialize our products. We expect our expenses to increase in connection with our anticipated activities, particularly as we continue research and development, initiate and conduct clinical trials, and seek marketing approval for our product candidates. Until such time as we receive approval from the FDA and other regulatory authorities for our product candidates, we will not be permitted to sell our products and therefore will not have product revenues from the sale of products. For the foreseeable future we will have to fund all of our operations and capital expenditures from equity and debt offerings, cash on hand, licensing and collaboration fees and grants, if any.

We will need to raise additional capital to fund our operations and meet our current timelines and we cannot be certain that funding will be available on acceptable terms on a timely basis, or at all. The amount of government funding available for grants is dependent upon governmental budgets over which we have no control and which change with new administrations. Based on our current plans, we expect that our current cash will be sufficient to fund operations into the first quarter of 2027 and will only be sufficient to cover overhead costs, close out of the VIRAGE Phase 2b clinical trial, commence and complete a potential Phase 2a study evaluating VCN-01 dosing frequency, exploratory VCN-01 manufacturing scale-up activities, regulatory interactions regarding proposed VCN-01 clinical trials in PDAC and retinoblastoma, and preclinical studies supporting VCN-01 and VCN-12, the first candidate from our VCN-X discovery program. We believe our cash will also be sufficient to fund our committed obligations under the terms of the Purchase Agreement related to the Acquisition, but may not be sufficient for additional trials of VCN-01 or SYN-004, or to complete the last cohort of the Phase 1a/2a clinical trial of SYN-004, which are expected to require significant cash expenditures. In addition, based on the significant anticipated cost of a Phase 3 clinical program in a broad indication for SYN-004, we expect it will not be feasible for us to initiate and complete this trial at this time without a partner given the capital constraints tied to our current market cap and share price. We intend to focus our capital on our VCN-01 clinical trials and do not intend to provide further funding for our development of SYN-004 internally but intend to out-license or partner further development of SYN-004. Further development of VCN's product candidates will require additional funding. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience significant dilution. Any debt financing, if available, may involve restrictive covenants that may impact our ability to conduct our business and also have a dilutive effect on our stockholders. A failure otherwise to secure additional funds when needed in the future whether through an equity or debt financing or a sufficient amount of capital without a strategic partnership could result in us being unable to complete planned preclinical and clinical trials or obtain approval of our product candidates from the FDA and other regulatory authorities. In addition, we could be forced to delay, discontinue or curtail product development, forgo sales and marketing efforts, and forgo licensing in attractive business opportunities, cease operations, sell or otherwise liquidate our assets or reorganize the Company, or complete a combination of the foregoing. Our ability to raise capital through the sale of securities may be limited by the rules of the SEC and NYSE American that place limits on the number and dollar amount of securities that may be sold. There can be no assurances that we will be able to raise the funds needed, especially in light of the fact that our ability to sell securities registered on our registration statement on Form S-3 will be limited until such time the market value of our voting securities held by non-affiliates is $75 million or more. We also may be required to seek collaborators for our product candidates at an earlier stage than otherwise would be desirable and on terms that are less favorable than might otherwise be available.

We expect to continue to incur significant operating and capital expenditures and we will need additional funds to support our operations, and such funding may not be available to us on acceptable terms, or at all, which would force us to delay, reduce or suspend our research and development programs and other operations or commercialization efforts.

We have a history of losses and we have incurred, and will continue to incur, substantial losses and negative operating cash flow. Even if we succeed in developing and commercializing one or more of our product candidates, we may still incur substantial losses for the foreseeable future and may not sustain profitability. We anticipate a need for additional employees as we undertake later stage clinical trials.

Further development of VCN-01 and pipeline OV product candidates will require additional expenditures. We also expect to continue to incur significant operating and capital expenditures and anticipate that our expenses will substantially increase in the foreseeable future as we do the following:

- continue to undertake preclinical development of our OV pipeline and mid and late-stage clinical trials for our product candidates;
- complete a potential Phase 2a study evaluating VCN-01 dosing frequency
- seek regulatory approvals for our product candidates;
- develop our product candidates for commercialization;
- implement additional internal systems and infrastructure;
- license or acquire additional technologies;
- lease additional or alternative office facilities;
- manufacture product for clinical trials and commercial use; and
- hire additional personnel, including members of our management team.

We expect to experience negative cash flow for the foreseeable future as we fund our development and clinical programs with capital expenditures. As a result, we will need to raise additional capital or generate significant revenues in order to achieve and maintain profitability. We may not be able to generate these revenues or achieve profitability in the future. Our failure to achieve or maintain profitability, which we do not anticipate will occur in the near future, could negatively impact the value of our Common Stock and underlying securities. There can be no assurance that funding will be available on acceptable terms on a timely basis, or at all. The various ways that we could raise capital carry potential risks. Any additional sources of financing will likely involve the issuance of our equity securities, which will have a dilutive effect on our stockholders. If we raise funds through collaborations and licensing arrangements, we might be required to relinquish significant rights to our technologies or tests or grant licenses on terms that are not favorable to us. The amount of government funding available for grants is dependent upon governmental budgets over which we have no control and which change with new administrations.

The actual amount of funds we will need to operate is subject to many factors, some of which are beyond our control.

The actual amount of funds we will need to operate is subject to many factors, some of which are beyond our control. These factors include, without limitation, the following:

- the progress of our research activities and ability to attract patients;
- the number and scope of our research programs;
- the progress of our preclinical and clinical development activities;
- the progress of the development efforts of parties with whom we have entered into research and development agreements and amount of funding received from partners and collaborators;

- our ability to maintain current research and development licensing arrangements and to establish new research and development and licensing arrangements;
- our ability to achieve our milestones under licensing arrangements;
- the costs associated with manufacturing-related services to produce materials for use in our clinical trials;
- the costs involved in prosecuting and enforcing patent claims and other intellectual property rights;
- the costs incurred to screen and enroll patients; and
- the costs and timing of regulatory approvals.

We have based our estimate on assumptions that may prove to be wrong. We may need to obtain additional funds sooner or in greater amounts than we currently anticipate. Potential sources of financing include strategic relationships, public or private sales of our shares or debt and other sources. Additionally, we may seek to access the public or private equity markets when conditions are favorable due to our long-term capital requirements. We do not have any committed sources of financing at this time, and it is uncertain whether additional funding will be available when we need it on terms that will be acceptable to us, or at all.

We currently have a limited operating history as an oncology company, no products approved for commercial sale, have no significant source of revenue and may never generate significant revenue.

We are a clinical-stage biopharmaceutical company that began to focus on development of OVs for treatment of various types of cancer in 2022. We have never generated any product revenue, do not expect to generate revenue in the near future and do not have any products approved for sale. Our operations to date have been primarily focused on developing our product candidates. We have not yet successfully obtained marketing approval, manufactured any product candidate at commercial scale, or conducted sales and marketing activities that will be necessary to successfully commercialize our product candidates. Consequently, predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing product candidates.

All of our existing product candidates are in various stages of development and will require extensive additional clinical evaluation, regulatory review and approval, significant marketing efforts and substantial investment before they could provide us with any revenue. As a result, even if we successfully develop, achieve regulatory approval and commercialize our products, we may be unable to generate revenue for many years, if at all. We do not anticipate that we will generate revenue from product sales for at least several years, if at all. If we are unable to generate revenue from product sales, we will not become profitable, and we may be unable to continue our operations.

Our ability to generate revenue depends heavily on:

- our ability to raise additional capital on a timely basis to continue to fund our clinical trials;
- demonstration in current and future clinical trials that our lead product candidate, VCN-01 (zabilugene almadenorepvec), as well as each of our other product candidates, is safe and effective; and
- our ability to seek and obtain regulatory approvals, including with respect to the indications we are seeking.

Even if we receive regulatory approval for the sale of any of our product candidates, we do not know when we will begin to generate revenue, if at all. Our ability to generate revenue depends on a number of factors, including our ability to:

- set an acceptable price for our products and obtain coverage and adequate reimbursement from third-party payors;
- establish sales, marketing, manufacturing and distribution systems;
- add operational, financial and management information systems and personnel, including personnel to support our clinical, manufacturing and planned future clinical development and commercialization efforts and operations as a public company;

- develop manufacturing capabilities for bulk materials and manufacture commercial quantities of product candidates at acceptable cost levels;
- achieve broad market acceptance of our product candidates in the medical community and with third-party payors and consumers;
- attract and retain an experienced management and advisory team;
- successfully launch commercial sales of our products, whether alone or in collaboration with others; and
- maintain, expand and protect our intellectual property portfolio.

Because of the numerous risks and uncertainties associated with development and manufacturing, we are unable to predict if we will generate revenue. If we cannot successfully execute on any of the factors listed above, our business may not succeed, we may never generate revenue and your investment will be adversely affected.

Although we currently believe that our internal controls are effective, we have identified material weaknesses in our internal controls in the past, and we cannot provide assurances that additional material weaknesses will not occur in the future

If our internal control over financial reporting or our disclosure controls and procedures are not effective, we may not be able to accurately report our financial results, prevent fraud, or file our periodic reports in a timely manner, which may cause investors to lose confidence in our reported financial information and may lead to a decline in our stock price. Our management is responsible for establishing and maintaining adequate internal control over our financial reporting, as defined in Rule 13a- 15(f) under the Exchange Act. Based on our assessment, we have concluded that as of December 31, 2025 our internal control over financial reporting and our disclosure controls and procedures are effective. However, during 2023 and the first three quarters of 2024, we identified certain material weaknesses in our internal controls, which led to a determination that our controls were not effective during those periods. While we took remedial action to address the previously identified material weaknesses in 2024 and we believe that our internal control over financial reporting have been, and continue to be, effective since December 31, 2024, we cannot provide any assurance that such remedial measures, or any other remedial measures we take from time to time, will continue to be effective. If we fail to maintain effective internal control over financial reporting, we may not be able to accurately report our financial results, detect or prevent fraud, or file our periodic reports in a timely manner, which may, among other adverse consequences, cause investors to lose confidence in our reported financial information and lead to a decline in our stock price. In addition, a material weakness will not be considered remediated until the applicable controls operate for a sufficient period of time and management has concluded, through testing, that these controls are designed and operating effectively. Although management believes that the previously identified material weaknesses were remediated prior to December 31, 2024, there can be no assurance that our internal control over financial reporting, as modified, will enable us to identify or avoid material weaknesses in the future.

We expect to seek to raise additional capital in the future, which may be dilutive to stockholders or impose operational restrictions.

We expect to seek to raise additional capital in the future to help fund development of our proposed products. If we raise additional capital through the issuance of equity or of debt securities, the percentage ownership of our current stockholders will be reduced. We may also enter into strategic transactions, issue equity as consideration for acquisitions or part of license issue fees to our licensors, compensate consultants or settle outstanding payables using equity that may be dilutive. We are authorized to issue 350,000,000 shares of Common Stock, of which 45,892,668 shares of Common Stock were outstanding as of March 10, 2026. If all of the unissued authorized shares were issued stockholders ownership percentage will be significantly diluted.

In order to raise additional capital, we may in the future offer additional shares of our Common Stock or other securities convertible into or exchangeable for our Common Stock at prices that may not be the same as the price per share paid by existing stockholders, thereby subjecting such stockholders to dilution. Our stockholders may experience additional dilution in net book value per share and any additional equity securities may have rights, preferences and privileges senior to those of the holders of our Common Stock.

We may sell shares or other securities in any other offering at a price per share that is less than the price per share paid by existing stockholders, and investors purchasing shares or other securities in the future could have rights superior to existing stockholders. The price per share at which we sell additional shares of our Common Stock, or securities convertible or exchangeable into Common Stock, in future transactions may be higher or lower than the price per share paid by existing stockholders.

Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or our guidance.

Our quarterly and annual operating results may fluctuate significantly in the future, which makes it difficult for us to predict our future operating results. The Purchase Agreement entered into in connection with the Acquisition requires that we make certain cash payments to Grifols upon attainment of certain milestones, which payments may vary significantly from period to period and any such variance could cause a significant fluctuation in our operating results from one period to the next. As discussed elsewhere in this Annual Report, the payment of $5.0 million of contingent consideration earned by Grifols pursuant to the Acquisition has been deferred pending ongoing discussions with Grifols. From time to time, we may enter into collaboration agreements with other companies that include development funding and significant upfront and milestone payments and/or royalties, which may become an important source of our revenue. Accordingly, our revenue may depend on development funding and the achievement of development and clinical milestones under any potential future collaboration and license agreements and sales of our products, if approved. These upfront and milestone payments may vary significantly from period to period and any such variance could cause a significant fluctuation in our operating results from one period to the next. In addition, our manufacturing and clinical trial expenses, which are anticipated to be significant, may fluctuate significantly quarter to quarter based upon whether or not we are engaged in clinical trials or manufacturing our product candidates, and timing of our process development work. Furthermore, we measure compensation cost for stock-based awards made to employees at the grant date of the award, based on the fair value of the award as determined by the Board of Directors, and recognize the cost as an expense over the employee's requisite service period. As the variables that we use as a basis for valuing these awards change over time, our underlying stock price and stock price volatility, the magnitude of the expense that we must recognize may vary significantly. Furthermore, our operating results may fluctuate due to a variety of other factors, many of which are outside of our control and may be difficult to predict, including the following:

- the timing and cost of, and level of investment in, research and development activities relating to current product candidates and any future product candidates, which will change from time to time;
- our ability to enroll patients in clinical trials and the timing of enrollment;
- the timing and cost of manufacturing our current product candidates and any future product candidates, which may vary depending on FDA guidelines and requirements, the quantity of production and the terms of our agreements with manufacturers;
- expenditures that we will or may incur to acquire or develop additional product candidates and technologies;
- the timing and outcomes of clinical studies or competing product candidates;
- changes in the competitive landscape of our industry, including consolidation among our competitors or partners;
- any delays in regulatory review or approval of our current product candidates or any of our future product candidates;
- the level of demand for our current product candidates and any future product candidates, should they receive approval, which may fluctuate significantly and be difficult to predict;
- the risk/benefit profile, cost and reimbursement policies with respect to our products candidates, if approved, and existing and potential future drugs that compete with our product candidates;
- competition from existing and potential future drugs that compete with our current product candidates or any of our future product candidates;
- our ability to commercialize our current product candidates or any future product candidate inside and outside of the United States, either independently or working with third parties;
- our ability to establish and maintain collaborations, licensing or other arrangements;
- our ability to adequately support future growth;

- potential unforeseen business disruptions that increase our costs or expenses;
- future accounting pronouncements or changes in our accounting policies; and
- the changing and volatile global economic environment.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our Common Stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated revenue and/or earnings guidance we may provide.

If our acquired intangible assets become impaired in the future as was the case in 2024, we may be required to record a significant charge to earnings.

We regularly review acquired intangible assets for impairment when events or changes in circumstances indicate that the carrying value may not be recoverable. We test goodwill and indefinite-lived intangible assets for impairment at least annually. Factors that may be considered a change in circumstances, indicating that the carrying value of the intangible assets may not be recoverable, include: macroeconomic conditions, such as deterioration in general economic conditions; industry and market considerations, such as deterioration in the environment in which we operate; cost factors, such as increases in labor or other costs that have a negative effect on earnings and cash flows; our financial performance, such as negative or declining cash flows or a decline in actual or planned revenue or earnings compared with actual and projected results of relevant prior periods; other relevant entity-specific events, such as changes in management, key personnel, strategy, or customers; and sustained decreases in share price.

A prolonged U.S. federal government shutdown could materially and adversely affect our business and operations.

Any disruption in the operations of the U.S. government, including as a result of the recent or future temporary or prolonged shutdowns resulting from the failure of Congress to enact appropriations bills or raise the federal debt ceiling, could materially and adversely affect our business, operations and financial condition. Recently, beginning on October 1, 2025, the U.S. federal government shut down and remained shut down through November 12, 2025, and again beginning on January 31, 2026 through February 3, 2026, during which times certain regulatory agencies, such as the FDA and the SEC, furloughed critical employees and stopped critical activities. Additionally, on October 10, 2025, the U.S. government implemented substantial layoffs and workforce reductions in connection with the federal government shutdown, which resulted in the suspension or delay of various government-funded programs. Furthermore, the recent federal government shutdown has resulted, and may continue for a prolonged period of time to result, in reduced availability of government services, and suspension or delay of activities by key agencies that regulate, fund, or interact with our business, including the SEC, the FDA, the Department of Health and Human Services, and the U.S. Patent and Trademark Office. As a result, the review and approval of our filings, applications, and submissions could be delayed, and we may be unable to access or rely upon certain government data or systems. In particular, it may lead to disruptions and delays in FDA's review and oversight of our product candidates and impact the FDA's ability to provide timely feedback on our development program or pending applications.

Additionally, a prolonged or future shutdown of the U.S. federal government could materially impact the operations of the SEC. For example, the SEC announced that during the recent U.S. federal government shutdowns, it would not review or declare registration statements effective. In the event of an extended shutdown, the SEC may operate with limited staff or suspend certain functions altogether, which could delay the review or effectiveness of our filings, including registration statements or other financing-related disclosures. Such delays could adversely affect our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue to fund our operations.

Government shutdowns, if prolonged, can significantly impact the ability of government agencies upon which rely, such as the FDA and SEC, to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Even the threat of a government shutdown or prolonged budget negotiation uncertainty may adversely affect the broader U.S. economy, investor confidence, and capital markets. Such conditions could negatively impact our access to financing, timing of capital-raising transactions, and the liquidity or trading volume of our securities. Accordingly, the current or future federal government shutdowns, or uncertainty regarding the continuity of government operations, could have a material adverse effect on our business, results of operations, and stock price.

Federal budget and debt-ceiling disputes may adversely affect capital markets and our financing activities.

Moreover, the uncertainty surrounding government funding debates and debt-ceiling negotiations can negatively affect market conditions, investor sentiment, and the liquidity of small-cap and microcap issuers such as ours. If market volatility or trading disruptions were to occur during the current or future government shutdowns, our ability to execute at-the-market offerings or other financing transactions under our effective shelf registration statement or through private equity offerings could be materially impaired.

Accordingly, any federal government shutdown or protracted budget impasse could materially and adversely affect our regulatory compliance, financing options and capabilities, and overall financial condition.

RISKS RELATED TO OUR BUSINESS

Prior to 2022, we had not conducted any research and development activities directed to cancer diagnosis, treatment or prevention and there can be no assurance that we will successfully be able to do so.

Prior to the VCN Acquisition, our focus was on the microbiome and our research and development was focused primarily on therapeutics for various microbiome related diseases. Upon the VCN Acquisition, our focus has shifted to the use of OVs to treat cancer. Although members of our management and scientific/development teams have experience in the research and development of cancer treatments, we may not be successful as a company with such focus.

In the past OVs have experienced certain safety and efficacy challenges.

Although current clinical trials of OVs have supported their role as a potential treatment for cancer, there is the risk of virus-related toxicities *in vivo* and possible transmission to patients' contacts, such as other patients and health care workers. In recent years, clinical trials to address these concerns have been conducted. Any such transmission by VCN-01 (zabilugene almadenorepvec) or a competitor would have an adverse impact on our future OV research and development efforts. Likewise, a number of OVs have previously failed to meet their primary endpoints in advanced clinical trials, potentially reducing investor and partner interest or confidence in the development of new such therapies, however well differentiated they are from previous products.

Our research and development efforts may not result in commercially successful products and technologies, which may limit our ability to achieve profitability.

We must continue to explore opportunities that may lead to new products and technologies. To accomplish this, we must commit substantial efforts, funds, and other resources to research and development. A high rate of failure is inherent in the research and development of new products and technologies. Any such expenditures that we make will be made without any assurance that our efforts will be successful. Failure can occur at any point in the process, including after significant funds have been invested.

The success of our business currently depends on our development, approval and commercialization of our lead product candidate, VCN-01 (zabilugene almadenorepvec). Our ongoing Phase 1b/2a clinical trial of SYN-004 for the prevention of aGVHD in allogeneic HCT recipients, and ongoing early-stage clinical trials of VCN-01 are not designed as registrational clinical trials and we currently do not have the necessary funding to complete any late stage registrational clinical trials. There are many uncertainties known and unknown that may affect the outcome of future clinical trials. All of our product candidates, including VCN-01, SYN-004 (ribaxamase), and SYN-020 will require additional clinical and non-clinical development, regulatory review and approval in multiple jurisdictions, substantial investment, access to sufficient commercial manufacturing capacity and significant marketing efforts before we can generate any revenue from product sales. Although Rasayana has assumed all responsibility and costs for the development and commercialization of SYN-020, and has committed to use reasonable commercial efforts to develop and commercialize SYN-020 and to meet certain development milestones set forth in the Rasayana License Agreement, no assurances can be made that they will be successful in further developing or obtaining regulatory approval of products related thereto or that we will receive any development milestone payments or sales milestone payments from Rasayana in connection therewith. Regardless of whether our clinical trials (or, in the case of SYN-020, Rasayana's clinical trials) are deemed to be successful, promising new product candidates may fail to reach the market or may only have limited commercial success because of efficacy or safety concerns, failure to achieve positive clinical outcomes, inability to obtain necessary regulatory approvals or satisfy regulatory criteria, limited scope of approved uses, excessive costs to manufacture, the failure to establish or maintain intellectual property rights, or infringement of the intellectual property rights of others. Failure to obtain regulatory approvals of VCN-01, SYN-004 (ribaxamase) or SYN-020 in a timely manner would have a material adverse impact on our business. Even if we successfully develop VCN-01, SYN-004 (ribaxamase), or other new products or enhancements, or if Rasayana successfully develops SYN-020 or new products or enhancements covered by the Rasayana License Agreement, they may be quickly rendered obsolete by changing customer preferences, changing industry standards, or competitors' innovations. Innovations may not be quickly accepted in the marketplace because of, among other things, entrenched patterns of clinical practice or uncertainty over third-party reimbursement. We cannot state with certainty when or whether any of our products under development will be launched, whether we will be able to develop, license, or otherwise acquire drug candidates or products, or whether any products will be commercially successful. Failure to launch successful new products or new indications for existing products may cause our products to become obsolete, which may limit our ability to achieve profitability.

We have in the past, and may continue to seek to, form or seek strategic alliances or enter into additional licensing arrangements in the future, and we may not realize the benefits of such alliances or licensing arrangements.

As discussed elsewhere in this Annual Report on Form 10-K, on February 17, 2026, we entered into the Rasayana License Agreement with Rasayana, pursuant to which we granted Rasayana an exclusive worldwide license with the right to grant sublicenses to research, develop, manufacture and commercialize any Product (as such term is defined in the Rasayana License Agreement), which includes SYN-020, comprising, containing, or covered by the Licensed IP (as such term is defined in the Rasayana License Agreement) and/or devised, developed, or produced using the Licensed IP. We are also considering licensing and partnership opportunities for the further development of our SYN-004 (ribaxamase) product candidate, and may consider other strategic opportunities for this product candidate or our other product candidates from time to time. We may form or seek strategic alliances, create joint ventures or collaborations or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our product candidates and any future product candidates that we may develop. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates because they may be deemed to be at too early a stage of development for collaborative effort and third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy. If we license products or businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture. We cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction. Any delays in entering into new strategic partnership agreements related to our product candidates could delay the development and commercialization of our product candidates in certain geographies for certain indications, which would harm our business prospects, financial condition and results of operations.

We rely on licenses to use various technologies that are material to our business and we may not be able to retain rights licensed to us by others to commercialize key products and may not be able to establish or maintain the relationships we need to develop, manufacture, and market our products.

In addition to our own patent applications, we also currently rely on licensing agreements with third party patent holders/licensors for our products. We have entered into license agreements upon which our OV technology is dependent. If we breach the terms of any of our license agreements or collaborations, including any failure to make royalty payments required thereunder or failure to reach certain developmental milestones or fulfill our obligations under the agreements could result in a termination of the agreements. The Technology Transfer Agreement") between VCN and IDIBELL for the exclusive license of the right to use a Spanish patent number P200901201 titled "Oncolytic adenoviruses for treating cancer" provides IDIBELL with the right to revoke the license if VCN ceases business activities for a continuous year or ceases to utilize the technology subject of the Technology Transfer Agreement, uses the technology in violation of the principals of IDIBELL or ICO or stops maintaining the patent licensed under the Technology Transfer Agreement. The ICO License provides that VCN and its sublicensees have an obligation to use all diligent and commercially reasonable efforts for the exploitation of the patent, otherwise, ICO may proceed to recover the license. The "IDIBELL/ICO License Agreement provides that the licensors have the right to revoke the IDIBELL/ICO License Agreement if VCN during a continuous period of two years abandons its research or development activities of the licensed patent or activities aimed at exploitation of the resulting products. If any license were to terminate and we were to lose the right to commercialize our products, our business opportunity would be adversely affected. Furthermore, we currently have very limited product development capabilities, and limited marketing or sales capabilities. For us to research, develop, and test our product candidates, we would need to contract with outside researchers, in most cases those parties that did the original research and from whom we have licensed the technologies.

We can give no assurances that any of our issued patents licensed to us or any of our other patent applications will provide us with significant proprietary protection or be of commercial benefit to us. Furthermore, the issuance of a patent is not conclusive as to its validity or enforceability, nor does the issuance of a patent provide the patent holder with freedom to operate without infringing the patent rights of others.

We may incur additional expenses in connection with our licenses and collaboration arrangements and our development of our product candidates.

VCN's collaboration agreements require that Theriva Biologics S.L. engage in certain research and development activities that require additional expenditures. Our agreement with Washington University may require that we initiate certain studies and file or have accepted an NDA within a certain amount of time, each of which are costly and will require additional expenditures. Although all manufacturing, preclinical studies and human clinical trials are expensive and difficult to design and implement, costs associated with the manufacturing, research and development of biologic product candidates are generally greater in comparison to small molecule product candidates. Due to our small work force, we expect in future years to require additional personnel to support our later stage research and development efforts. Manufacturing of VCN-01 (zabilugene almadenorepvec) and SYN-004 (ribaxamase) to support potential future clinical studies will require us to incur additional expenses.

Because development activities in our collaborations are sometimes determined pursuant to joint steering committees, future development costs associated with these programs may be difficult to anticipate and may exceed our expectations. Our actual cash requirements may vary materially from our current expectations for a number of other factors that may include, but are not limited to, unanticipated technical challenges, enrollment challenges, changes in the focus and direction of our development activities or adjustments necessitated by changes in the competitive landscape in which we operate. If we are unable to continue to financially support such collaborations due to our own working capital constraints, we may be forced to delay our activities. If we are unable to obtain additional financing on terms acceptable to us or at all, we may be forced to seek licensing partners or discontinue development.

Developments by competitors may render our products or technologies obsolete or non-competitive.

The pharmaceutical and biotechnology industries, including the OV industry and the monoclonal antibody industry, are characterized by rapidly evolving technology and intense competition. Our competitors include major multi-national pharmaceutical companies and biotechnology companies developing both generic and proprietary therapies to treat serious diseases. Many of our competitors have drugs that have already been commercialized and therefore benefit from being first to market their products. Many of these companies are well-established and possess technical, human, research and development, financial, and sales and marketing resources significantly greater than ours. In addition, many of our potential competitors have formed strategic collaborations, partnerships and other types of joint ventures with larger, well established industry competitors that afford these companies' potential research and development and commercialization advantages in the therapeutic areas we are currently pursuing. Academic research centers, governmental agencies and other public and private research organizations are also conducting and financing research activities which may produce products directly competitive to those being developed by us. In addition, many of these competitors may be able to obtain patent protection, obtain FDA and other regulatory approvals and begin commercial sales of their products before us, including for different indications of the same active ingredients that comprise our pipeline products. These competitors will compete with us in product sales as well as recruitment and retention of qualified scientific and management personnel, establishment of clinical trial sites and patient enrollment for clinical trials, as well as in the acquisition of technologies and technology licenses complementary to our programs or advantageous to our business. Companies pursuing clinical development of modified oncolytic adenoviruses include AdCure Bio LLC, Calidi Biotherapeutics, Inc., Candel Therapeutics, Inc., CG Oncology, Inc., Elicera Therapeutics AB, EpicentRx, Inc., GeneMedicine, Co Ltd., Lokon Pharma AB, Memgen, Inc., Multivir, Inc., NewGenPharm Incorporation, Oncolys BioPharma, Inc., Orca Therapeutics B.V., Akamis Bio Ltd. (formerly PsiOxus Therapeutics Ltd), Shanghai Sunway Biotech Co., Ltd, Tessa Therapeutics, Theolytics Ltd., TILT Biotherapeutics, Ltd., Urogen Pharma, and Valo Therapeutics Oy. OV products have been or are being developed using other virus backbones, including: arenavirus (Hookipa Pharma, Inc.); Coxsackie virus (Viralytics Ltd., Oncorus Inc.); herpes simplex virus (Amgen, Inc., Candel Therapeutics, Inc., Daiichi Sankyo Company Ltd., Replimune, Inc., Takara Bio, Inc., Treovir LLC, Virogin Biotech, Inc., Wuhan Binhui Biotechnology Co., Ltd.); Maraba virus (Turnstone Biologics, Inc.); measles virus (Themis Biosciences GmbH, Vyriad, Inc.); myxoma virus (OncoMyx Therapeutics, Inc.); parvovirus (Oryx GmbH & Co. KG), reovirus (Oncolytics Biotech, Inc.); Seneca Valley virus (Seneca Therapeutics Inc., Oncorus Inc.); vesicular stomatitis virus (Boehringer Ingelheim, Cytonus Therapeutics, Inc., Vyriad, Inc.); and vaccinia viruses (Genelux Corporation, Imugene Ltd, Joint Biosciences Ltd, KaliVir Immunotherapeutics LLC, SillaJen, Inc., Transgene SA, Turnstone Biologics, Corp.). In addition, academic research centers may develop technologies that compete with our VCN-01 (zabilugene almadenorepvec), SYN-004 (ribaxamase) and SYN-020 products and our other technologies. Should clinicians or regulatory authorities view alternative therapeutic regiments as more effective than our products, this might delay or prevent us from obtaining regulatory approval for our products, or it might prevent us from obtaining favorable reimbursement rates from payers, such as Medicare, Medicaid, hospitals and private insurers.

Not only do our product candidates compete with other product candidates being developed for similar or the same indications, we also compete for employees, clinical trial sites, and participants in clinical trials.

We may seek to selectively establish collaborations, and, if we are unable to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans.

Our product development programs and the potential commercialization of our clinical product candidates will require substantial additional cash to fund expenses. For some of our product candidates, we may decide to collaborate with governmental entities or additional pharmaceutical and biotechnology companies for the development and potential commercialization of our product candidates.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative product candidates for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with our product candidate.

If the parties we depend on for supplying substance raw materials for our product candidates and certain manufacturing-related services do not timely supply these products and services in sufficient quality or quantity, or if current drug supply becomes unusable, it may delay or impair our ability to develop, manufacture and market our product candidates.

We rely on suppliers for the substance raw materials of our product candidates and third parties for manufacturing-related services to produce material that meets appropriate content, quality and stability standards and use in clinical trials of our products and, after approval, for commercial distribution. To succeed, clinical trials require adequate supplies of study material, which may be difficult or uneconomical to procure or manufacture and there can be no assurance that we will successfully procure such study material when needed, if at all, or even if procured, that we can do so in quantities and in a timely manner to allow our clinical trials to proceed as planned. Drug supply, once produced, is stored at clinical trial sites and vendor depots and we rely on these locations to maintain and protect the drug supply appropriately. Moreover, clinical drug supply has a finite shelf-life that may not be fully established prior to initiating early-stage clinical trials. We and our suppliers and vendors may not be able to (i) produce our study material to appropriate standards for use in clinical studies, (ii) perform under any definitive manufacturing, supply or service agreements with us, or (iii) remain in business for a sufficient time to successfully produce and market our product candidates, or (iv) prevent the drug supply from becoming unusable due to damage, loss or shelf-life expiration. If we do not maintain important manufacturing and service relationships, we may fail to find a replacement supplier or required vendor or manufacturer which could delay or impair our ability to conduct clinical trials and obtain regulatory approval for our products and substantially increase our costs or deplete profit margins, if any. If we do find replacement manufacturers and vendors, we may not be able to enter into agreements with them on terms and conditions favorable to us and there could be a substantial delay before a new facility could be qualified and registered with the FDA and foreign regulatory authorities.

The third-party manufacturers of the active pharmaceutical ingredient (API) and drug product for our lead product candidates, VCN-01 (zabilugene almadenorepvec), and SYN-004 (ribaxamase), are established cGMP manufacturers. For all other therapeutic areas, we have not yet established cGMP manufacturers for our biologic and drug candidates. We have used only one API manufacturer for each of our product candidates (VCN-01, SYN-004 and SYN-020) (prior to entering into the Rasayana License Agreement) used in clinical trials to date. Although we believe additional manufacturers are available, if any of our manufacturers were to limit or terminate production or otherwise fail to meet the quality or delivery requirements needed to satisfy the supply commitments, the process of locating and qualifying alternate sources could require up to several months, during which time our production could be delayed. Any curtailment in the availability of our product candidates could have a material adverse effect on our business, financial position and results of operations. In addition, because regulatory authorities must generally approve raw material sources for pharmaceutical products, changes in raw material suppliers may result in production delays or higher raw material costs.

The manufacture of our product candidates requires significant expertise and manufacturers may encounter difficulties in production, particularly in scaling up production. These problems include difficulties with production costs and yields, quality control, including stability of the product and quality assurance testing, shortages of qualified personnel, as well as compliance with federal, state and foreign regulations. We may experience longer than expected lead times with respect to the manufacture of clinical drug supply, which may result from the increase in manufacturing scale necessary to conduct our anticipated late-stage clinical trials and result in trial delays. Furthermore, during the COVID-19 pandemic, many manufacturers prioritized the manufacture of COVID-19 related products, increasing the manufacturing lead times for non-COVID-19 related products. If a pandemic should occur again and manufacturers prioritized the manufacture of pandemic related products, we may suffer a delay or interruption in the supply of clinical trial supplies. In addition, any future pandemic or other disruption to clinical trial participation or the production of clinical trial materials could delay the completion of our clinical trials, increase the costs associated with conducting our clinical trials and, depending upon the period of delay, require us to commence new clinical trials at significant additional expense or to terminate a clinical trial.

We are responsible for ensuring that each of our contract manufacturers comply with the cGMP requirements of the FDA and other regulatory authorities from which we seek to obtain product approval. While we oversee compliance, we do not have control over our manufacturers and their compliance with regulatory requirements. These requirements include, among other things, quality control, quality assurance and the maintenance of records and documentation. The approval process for NDAs includes a review of the manufacturer's compliance with cGMP requirements. We are responsible for regularly assessing a contract manufacturer's compliance with cGMP requirements through record reviews and periodic audits and for ensuring that the contract manufacturer takes responsibility and corrective action for any identified deviations.

A failure to comply with these requirements may result in fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or recall, or withdrawal of product approval. Furthermore, if our manufacturers fail to deliver the required commercial quantities on a timely basis and at commercially reasonable prices, we may be unable to meet demand for any approved products and would lose potential revenues.

For our clinical trials of VCN-01 (zabilugene almadenorepvec), we have or will administer our product candidate, VCN-01, in combination with other cancer drugs. Any problems obtaining these co-administered drugs could result in a delay or interruption in our clinical trials.

For our proposed pivotal clinical trial of VCN-01 in patients with PDAC, we plan to administer VCN-01 in combination with the already approved standard of care drugs, gemcitabine/nab-paclitaxel, for which there have previously been supply shortages. A potential clinical trial in refractory retinoblastoma is expected to administer VCN-01 in combination with topotecan. Our success will be dependent upon the continued use of and ability to obtain the co-administered drugs. We expect that in any other clinical trials we conduct for additional indications, our clinical product candidate will also be administered in combination with drugs owned by third parties. If any of the co-administered drugs that are used in our clinical trials are unavailable while the trials are continuing, the timeliness and commercialization costs could be impacted. In addition, if any of these other drugs are determined to have safety or efficacy problems, our clinical trials and commercialization efforts would be adversely affected.

If third-party vendors, upon whom we rely to conduct our preclinical studies or clinical trials, do not perform or fail to comply with strict regulations, these studies or trials may be delayed, terminated, or fail, or we could incur significant additional expenses, which could materially harm our business.

We have limited resources dedicated to designing, conducting and managing our preclinical studies and clinical trials. We rely on, third parties, including CROs, consultants and principal investigators, to assist us in designing, managing, conducting, monitoring and analyzing the data from our preclinical studies and clinical trials. We rely on these vendors and individuals to perform many facets of the clinical development process on our behalf, including conducting preclinical studies, the recruitment of sites and subjects for participation in our clinical trials, maintenance of good relations with the clinical sites, and ensuring that these sites are conducting our trials in compliance with the trial protocol and applicable regulations. If these third parties fail to perform satisfactorily, or do not adequately fulfill their obligations under the terms of our agreements with them, we may not be able to enter into alternative arrangements without undue delay or additional expenditures, and therefore the preclinical studies and clinical trials of our clinical product candidates may be delayed or prove unsuccessful.

Further, the FDA, the EMA, or similar regulatory authorities in other countries, may inspect some of the clinical sites participating in our clinical trials or our third-party vendors' sites to determine if our clinical trials are being conducted according to good clinical practices, or GCPs, or similar regulations. If we or a regulatory authority determine that our third-party vendors are not in compliance with, or have not conducted our clinical trials according to applicable regulations, we may be forced to exclude certain data from the results of the trial, or delay, repeat or terminate such clinical trials.

We may fail to retain or recruit necessary personnel, and we may be unable to secure the services of consultants.

As of March 12, 2026, we employed 15 full-time employees and 1 part-time employees, including employees located at Theriva Biologics' offices in Barcelona, Spain. We have also engaged clinical consultants to advise us on our clinical programs and regulatory consultants to advise us on our dealings with the FDA and other foreign regulatory authorities. Due to our small work force, we expect in future years to require additional personnel to support our later stage research and development efforts. We have been and may be required to retain additional consultants and employees in order to fulfill our obligations under our licenses and collaborations for our development of VCN-01 (zabilugene almadenorepvec), SYN-004 (ribaxamase), and our agreements with Washington University and other collaborators. Our future performance will depend in part on our ability to successfully integrate newly hired officers into our management team and our ability to develop an effective working relationship among senior management.

Certain of our directors, scientific advisors, and consultants serve as officers, directors, scientific advisors, or consultants of other biopharmaceutical or biotechnology companies that might be developing competitive products to ours. Other than corporate opportunities, none of our directors are obligated under any agreement or understanding with us to make any additional products or technologies available to us. Similarly, we can give no assurances, and we do not expect and stockholders should not expect, that any biomedical or pharmaceutical product or technology identified by any of our directors or affiliates in the future would be made available to us other than corporate opportunities. We can give no assurances that any such other companies will not have interests that are in conflict with our interests.

Losing key personnel or failing to recruit necessary additional personnel would impede our ability to attain our development objectives. There is intense competition for qualified personnel in the drug and biologic development areas, and we may not be able to attract and retain the qualified personnel we would need to develop our business.

We rely on independent organizations, advisors, and consultants to perform certain services for us, including handling substantially all aspects of regulatory approval, clinical management, manufacturing, marketing, and sales. We expect that this will continue to be the case. Such services may not always be available to us on a timely basis when we need them.

Inadequate funding for the FDA, the SEC and other government agencies, including from government shutdowns, or other disruptions to these agencies' operations, could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business and timelines.

Without appropriation of additional funding to federal agencies, our business operations related to our product development activities for the U.S. market could be impacted. The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. Disruptions at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Disruptions and personnel turnover, as a result of leadership changes, staff reductions or otherwise, at the FDA and other agencies may also slow the time necessary for new drugs and biologics or modifications to approved drugs and biologics to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. Changes and cuts in FDA staffing also could result in delays in the FDA's responsiveness or in its ability to review IND submissions or applications, issue regulations or guidance, or implement or enforce regulatory requirements in a timely fashion or at all.

Over the last several years the U.S. government has shut down several times and certain regulatory authorities, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. In addition, the current U.S. presidential administration has issued certain policies and Executive Orders directed towards reducing the employee headcount and costs associated with U.S. administrative agencies, including the FDA, and it remains unclear the degree to which these efforts may limit or otherwise adversely affect the FDA's ability to conduct routine activities. If a prolonged government shutdown occurs, or if renewed global health concerns, funding shortages or staffing limitations hinder or prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, including formal and informal interactions with product developers, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Global health crises may adversely affect our planned operations.

Our business and the business of the supplier of our clinical product candidates and the suppliers of the standard of care drugs that are administered in combination with our product candidates could be materially and adversely affected by the risks, or the public perception of the risks, related to a pandemic or other health crisis, such COVID-19. We experienced delays in patient enrollment due to the COVID-19 pandemic. If we should experience another pandemic, we could once again experience delays in patient enrollment and experience significant disruptions to our clinical development timelines. If we experience delays in patient enrollment or patients drop outs and we deem it necessary or advisable to improve patient recruitment by, among other things, opening additional clinical sites, we could incur increased clinical program expenses. Any such disruptions or delays would, and any such increased clinical program expenses could, adversely affect our business, financial condition, results of operations and growth prospects. In addition to delays or difficulties in enrolling patients in our clinical trials, we could experience the following disruptions that could severely impact our business and clinical trials, including:

- unwillingness of potential study participants to enroll in new clinical trials and/or visit healthcare facilities;
- postponement of enrollment in our clinical studies;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;

- interruption of key clinical trial activities, such as clinical site visits by study participants and clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others;

- limitations in employee resources that would otherwise be focused on the conduct of our clinical trials, including because of sickness of employees or their families, the desire of employees to avoid contact with large groups of people, or substantial numbers of resignations;

- delays in receiving approval from local regulatory authorities to initiate our planned clinical trials;

- delays in clinical site initiation due to understaffing in departments required for contracting and study start-up;

- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials;

- interruption in global shipping that may affect the manufacture and transport of clinical trial materials, such as investigational drug product used in our clinical trials;

- changes in local regulations as part of a response to a pandemic outbreak which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether;

- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees; and

- delay in the timing of interactions with the FDA and other regulatory agencies due to absenteeism by employees or by the diversion of their efforts and attention to approval of other therapeutics or other pandemic-related activities.

In addition, a significant outbreak of contagious diseases in the human population could result in the complete or partial closure of one or more manufacturing facilities which could impact our supply of our product candidates or the standard of care drugs that are administered in combination with our product candidates. In addition, an outbreak near where our clinical trial sites are located, has in the past, and may in the future impact our ability to recruit patients, and would likely delay our clinical trials, and could affect our ability to complete our clinical trials within the planned time periods. In addition, it could impact economies and financial markets, resulting in an economic downturn that could impact our ability to raise capital or slow down potential partnering relationships.

Our business and the business of the suppliers of our clinical product candidates were materially and adversely affected by the pandemic and post-pandemic workforce and supply-chain issues. While we are currently not experiencing material delays, such events could result in the delay or complete or partial closure of clinical trial sites or one or more manufacturing facilities which could impact our supply of our clinical product candidates. In addition, it could impact economies and financial markets, resulting in an economic downturn that could impact our ability to raise capital or slow down potential partnering relationships.

In addition, the outbreak of a pandemic could disrupt our operations due to absenteeism by infected or ill members of management or other employees, or absenteeism by members of management and other employees who elect not to come to work due to the illness affecting others in our office, or due to quarantines. Pandemics could also impact members of our Board of Directors resulting in absenteeism from meetings of the directors or committees of directors, and making it more difficult to convene the quorums of the full Board of Directors or its committees needed to conduct meetings for the management of our affairs.

The extent to which a pandemic may impact our business and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the outbreak, travel restrictions and social distancing in the United States and Spain, business closures or business disruptions and the effectiveness of actions taken in the United States, Spain, and other countries to contain and treat the disease.

Business disruptions could seriously harm our future revenue and financial condition and increase costs and expenses.

Our operations and those of our third-party suppliers and collaborators could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes or other extreme weather conditions, medical epidemics, labor disputes, war, changes in national or regional laws, regulations and economic policies, or other business interruptions. Any interruption could seriously harm our ability to timely proceed with any clinical programs or to supply product candidates for use in our clinical programs or during commercialization. For example, the COVID-19 pandemic did, at points, cause an interruption in our clinical trial activities. Additionally, supply chain disruptions impacted and may continue to impact our research activities. Continuing regional conflicts in Eastern Europe and the Middle East have created global security concerns that could have a lasting impact on regional and global economies, any or all of which could disrupt our supply chain, and despite the fact that we currently do not plan any clinical trials in Eastern Europe or the Middle East, may adversely impact the cost and conduct of our international clinical trials of our product candidates.

Unfavorable U.S. or global economic conditions could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and financial markets. A severe or prolonged economic downturn could result in a variety of risks to our business, including weakened demand for our technologies and our ability to raise additional capital when needed on favorable terms, if at all. Ongoing inflation in world economies may adversely affect us by increasing the costs associated with performing research and development on internal research initiatives and partnered programs. We may experience significant increases in the prices of labor, consumables, and other costs of doing business. In an inflationary environment, such cost increases may outpace our expectations, causing us to use cash faster than forecasted. A weak or declining economy may also strain our partners, possibly resulting in supply disruption, or cause delays in their payments to us. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

In addition, the global macroeconomic environment could be negatively affected by, among other things, pandemics or epidemics, instability in global economic markets, instability in the global credit markets, supply chain weaknesses, instability in the geopolitical environment as a result of the Russian war with Ukraine, the war in the Middle East, military or other action taken by the United States in foreign countries and other political tensions, and foreign governmental debt concerns. Such challenges have caused, and may continue to cause, uncertainty and instability in local economies and in global financial markets.

Changes to trade policy, including tariff and customs regulations, or failure to comply with such regulations may have an adverse effect on our reputation, business, financial condition and results of operations.

Changes in U.S. or international social, political, regulatory and economic conditions or in laws and policies governing trade, manufacturing, development and investment in the countries where we currently conduct our business could adversely affect our business, reputation, financial condition and results of operations. Changes or proposed changes in U.S. or other countries' trade policies may result in restrictions and economic disincentives on international trade. Changes to U.S. policy implemented by the U.S. Congress, the Trump administration or any new administration have impacted and may in the future impact, among other things, the U.S. and global economy, international trade relations, unemployment, immigration, healthcare, taxation, the U.S. regulatory environment, inflation and other areas. The U.S. government has recently imposed, or is currently considering imposing, tariffs on certain trade partners, including China, where we have engaged a vendor. Additionally, the United States has recently imposed significant tariffs on imports from other countries, including a baseline tariff of 10% on imports into the United States and higher tariffs on multiple designated countries, such as "reciprocal" tariffs at varying rates. Such tariffs have prompted retaliatory measures from several countries, which may further escalate. Certain of these tariffs have been subsequently paused or modified, and the situation remains fluid. While pharmaceutical products are currently excluded from the baseline and "reciprocal" tariffs imposed by the United States, such tariffs still apply to the raw materials and other products necessary for the manufacture and formulation of our product candidates. In addition, the U.S. Department of Commerce has initiated an investigation under Section 232 of the Trade Expansion Act of 1962, as amended, to determine the effects of importing pharmaceuticals and pharmaceutical ingredients on national security. This investigation may lead to the imposition of tariffs on pharmaceutical imports, consistent with the current U.S. administration's stated policy objective of reshoring pharmaceutical manufacturing to the United States. Further, in July 2025, the United States and the EU announced the framework of a trade agreement that generally imposes a 15% tariff on imports from the EU. Under this agreement, pharmaceutical products would not be subject to any future Section 232 investigation duties in excess of this 15% rate. The U.S. Supreme Court is currently considering legal challenges to tariffs imposed under the International Emergency Economic Powers Act, such as the baseline and reciprocal tariffs discussed above. The outcome of this decision could impact trade agreements entered into by the United States and the wider tariff environment in which we operate.

Tariffs, reciprocal tariffs, economic sanctions, embargoes, import or export licensing requirements and other changes in U.S. trade policy have in the past and could in the future trigger additional retaliatory actions by affected countries. Further, any emerging protectionist or nationalist trends (whether regulatory, or consumer-driven) either in the United States or in other countries could affect the trade environment. Our business, like many other corporations, would be impacted by changes to the trade policies of the United States and foreign countries (including governmental action related to tariffs, international trade agreements, or economic sanctions). Such changes have the potential to adversely impact the U.S. economy or certain sectors thereof, the global economy, and our industry, and as a result, could have a material adverse effect on our business, financial condition and results of operations.

We rely extensively on our information technology systems, and our systems and infrastructure face certain risks, including cybersecurity and data leakage risks.

We rely on our information technology systems and infrastructure to process transactions, summarize results and manage our business, including maintaining client and supplier information. In the ordinary course of business, we collect, store and transmit large amounts of confidential information, and it is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. Additionally, we utilize third parties, including cloud providers, to store, transfer and process data. Our information technology systems, as well as the systems of our suppliers and other partners, whose systems we do not control, are vulnerable to outages and an increasing risk of continually evolving deliberate intrusions to gain access to company sensitive information. The size and complexity of our information technology systems, and those of our third-party vendors with whom we contract, make such systems potentially vulnerable to service interruptions and security breaches from inadvertent or intentional actions by our employees, partners or vendors, from attacks by malicious third parties, or from intentional or accidental physical damage to our systems infrastructure maintained by us or by third parties. Data security incidents and breaches by employees and others with or without permitted access to our systems pose a risk that sensitive data may be exposed to unauthorized persons or to the public. Maintaining the secrecy of this confidential, proprietary, or trade secret information is important to our competitive business position. While we have taken steps to protect such information and invested in information technology, there can be no assurance that our efforts will prevent service interruptions or security breaches in our systems or the unauthorized or inadvertent wrongful use or disclosure of confidential information that could adversely affect our business operations or result in the loss, dissemination, or misuse of critical or sensitive information. A cyber-attack or other significant disruption involving our information technology systems, or those of our vendors, suppliers and other partners, could also result in disruptions in critical systems, corruption or loss of data and theft of data, funds or intellectual property. A breach of our security measures or the accidental loss, inadvertent disclosure, unapproved dissemination, misappropriation or misuse of trade secrets, proprietary information, or other confidential information, whether as a result of theft, hacking, fraud, trickery or other forms of deception, or for any other reason, could enable others to produce competing products, use our proprietary technology or information, or adversely affect our business or financial condition. We may be unable to prevent outages or security breaches in our systems. We remain potentially vulnerable to additional known or yet unknown threats as, in some instances, we, our suppliers and our other partners may be unaware of an incident or its magnitude and effects. We also face the risk that we expose our vendors or partners to cybersecurity attacks. Any or all of the foregoing could adversely affect our results of operations and our business reputation.

Our business and operations would suffer in the event of computer system failures.

Despite the implementation of security measures, our internal computer systems, and those of third parties on which we rely, are vulnerable to damage from computer viruses, malware, natural disasters, terrorism, war, telecommunication and electrical failures, cyber-attacks or cyber-intrusions over the internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization. The risk of a security breach or disruption, particularly through cyber-attacks or cyber-intrusions, including by computer hackers, foreign governments, and cyber-terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our current or future product development programs. For example, the loss of clinical trial data from completed or any future ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach was to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur material legal claims and liability, damage to our reputation, and the further development of our product candidates could be delayed.

Any failure to maintain the security of information relating to our patients, customers, employees and suppliers, whether as a result of cybersecurity attacks or otherwise, could expose us to litigation, government enforcement actions and costly response measures, and could disrupt our operations and harm our reputation.

Significant disruptions to our information technology systems or breaches of information security could adversely affect our business. In connection with the pre-clinical and clinical development, sales and marketing of our products and services, we may from time to time transmit confidential information. We also have access to, collect or maintain private or confidential information regarding our clinical trials and the patients enrolled therein, employees, and suppliers, as well as our business. Although we have instituted security measures, there can be no assurance that these security measures will be able to protect against cyberattacks. Cyberattacks are rapidly evolving and becoming increasingly sophisticated. It is possible that computer hackers and others might compromise our security measures, or security measures of those parties that we do business with now or in the future, and obtain the personal information of patients in our clinical trials, vendors, employees and suppliers or our business information. A security breach of any kind, including physical or electronic break-ins, computer viruses and attacks by hackers, employees or others, could expose us to risks of data loss, litigation, government enforcement actions, regulatory penalties and costly response measures, and could seriously disrupt our operations. Any resulting negative publicity could significantly harm our reputation, which could cause us to lose market share and have an adverse effect on our results of operations.

We may face particular data protection, data security and privacy risks in connection with the European Union's Global Data Protection Regulation and other privacy regulations.

Outside of the United States, the laws, regulations and standards in many jurisdictions apply broadly to the collection, use, and other processing of personal information. For example, in the European Union, the collection and use of personal data are governed by the provisions of the General Data Protection Regulation (the "GDPR"). The GDPR, together with national legislation, regulations and guidelines of the European Union. member states governing the processing of personal data, impose strict obligations on entities subject to the GDPR, including but not limited to: (i) accountability and transparency requirements, and enhanced requirements for obtaining valid consent from data subjects; (ii) obligations to consider data protection as any new products or services are developed and to limit the amount of personal data processed; (iii) obligations to comply with the data protection rights of data subjects; and (iv) obligations to report certain personal data breaches to governmental authorities and individuals. Data protection authorities from the different E.U. member states and other European countries may enforce the GDPR and national data protection laws differently, and introduce additional national regulations and guidelines, which adds to the complexity of processing European personal data. Failure to comply with the requirements of the GDPR and the related national data protection laws may result in significant monetary fines and other administrative penalties (the GDPR authorizes fines for certain violations of up to 4% of global annual revenue or €20 million, whichever is greater) as well as civil liability claims from individuals whose personal data was processed. Additionally, expenses associated with compliance could reduce our operating margins.

The GDPR also prohibits the transfer of personal data from the E.U. to countries outside of the E.U. unless made to a country deemed by the European Commission to provide adequate protection for personal data or accomplished by means of an approved data transfer mechanism (e.g., standard contractual clauses). Data protection authority guidance and enforcement actions that restrict companies' ability to transfer data may increase risk relating to data transfers or make it more difficult or impossible to transfer E.U. personal data to the U.S.

REGULATORY RISKS

If we do not obtain the necessary regulatory approvals in the U.S. and/or other countries we will not be able to develop or sell our product candidates.

We cannot assure you that we will receive the approvals necessary to commercialize any of our product candidates or any product candidates we acquire or develop in the future. We will need FDA approval to commercialize our product candidates in the U.S. and approvals from the FDA-equivalent regulatory authorities in foreign jurisdictions to commercialize our product candidates in those jurisdictions. We will be required to conduct clinical trials that will be costly and we currently do not have the funding to complete any registrational clinical trials. We cannot predict whether our clinical trials will demonstrate the safety and efficacy of our product candidates or if the results of any clinical trials will be sufficient to advance to the next phase of development or for approval from the FDA (or equivalent foreign regulatory authorities). We also cannot predict whether our research and clinical approaches will result in drugs or therapeutics that the FDA considers safe and effective for the proposed indications. The FDA has substantial discretion in the drug approval process. The approval process may be delayed by changes in government regulation, future legislation or administrative action or changes in FDA policy that occur prior to or during our regulatory review. Delays in obtaining regulatory approvals may prevent or delay commercialization of, and our ability to derive product revenues from our product candidates; and diminish any competitive advantages that we may otherwise believe that we hold.

Even if we comply with all FDA (or equivalent foreign regulatory authorities) requests, the FDA may ultimately reject one or more of our NDAs or BLAs. We may never obtain regulatory clearance for any of our product candidates. Failure to obtain FDA approval of any of our product candidates will severely undermine our business by leaving us without a saleable product, and therefore without any source of revenues, until another product candidate can be developed. There is no guarantee that we will ever be able to develop or acquire another product candidate.

In addition, the FDA (or equivalent foreign regulatory authorities) may require us to conduct additional pre-clinical and clinical testing or to perform post-marketing studies, as a condition to granting marketing approval of a product. The results generated after approval could result in loss of marketing approval, changes in product labeling, and/or new or increased concerns about the side effects or efficacy of a product. The FDA has significant post-market authority, including the explicit authority to require post-market studies and clinical trials, labeling changes based on new safety information, and compliance with FDA-approved risk evaluation and mitigation strategies. The FDA's exercise of its authority has in some cases resulted, and in the future could result, in delays or increased costs during product development, clinical trials and regulatory review, increased costs to comply with additional post-approval regulatory requirements and potential restrictions on sales of approved products.

In foreign jurisdictions, we must also receive approval from the appropriate regulatory authorities before we can commercialize any products, which can be time consuming and costly. Foreign regulatory approval processes generally include all of the risks associated with the FDA approval procedures described above but processes, requirements and timelines for approval by these agencies may differ significantly from the FDA. There can be no assurance that we will receive the approvals necessary to commercialize our product candidate for sale outside the United States.

If the FDA approves any of our product candidates, the labeling, manufacturing, packaging, adverse event reporting, storage, advertising, promotion and record-keeping for our products will be subject to ongoing FDA requirements and continued regulatory oversight and review. Our drug manufacturers and subcontractors that we retain will be required to comply with FDA and other regulations. We may also be subject to additional FDA post-marketing obligations. If we are not able to maintain regulatory compliance, we may not be permitted to market our product candidates and/or may be subject to product recalls, seizures, suspension of regulatory approval, suspension of production, injunctions or civil or criminal sanctions. The subsequent discovery of previously unknown problems with any marketed product, including adverse events of unanticipated severity or frequency, may result in restrictions on the marketing of the product, and could include withdrawal of the product from the market.

Clinical trials are very expensive, time-consuming, and difficult to design and implement.

Human clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. The clinical trial process is also time-consuming. We estimate that clinical trials for our product candidates would take at least several years to complete. Furthermore, failure can occur at any stage of the trials, and we could encounter problems that cause us to abandon or repeat clinical trials. Commencement and completion of clinical trials may be delayed by several factors, including:

- obtaining permission to proceed under an IND application with the FDA or foreign equivalent to commence clinical trials;
- delays in reaching an agreement with FDA or other ergaultory authorities on final trial design, including selection of control dose and efficacy endpoints
- identification of, and acceptable arrangements with, one or more clinical sites;
- obtaining IRB or IEC approval to commence clinical trials;
- obtaining IBC approval for use of a genetically modified organism;
- unforeseen safety issues;
- determination of dosing;
- lack of effectiveness during clinical trials;
- slower than expected rates of patient recruitment;
- inability to monitor patients adequately during or after treatment;
- lower than expected rates of patient completion of clinical trials;
- inability to obtain supply of our drug candidate in a timely manner;
- inability or unwillingness of medical investigators to follow our clinical protocols; and
- unwillingness of the FDA or foreign equivalent, IRBs/IECs, or IBCs to permit the clinical trials to be initiated.

In addition, we, IRBs/IECs or the FDA or foreign equivalent may suspend our clinical trials at any time if it appears that we are exposing participants to unacceptable health risks or if IRBs/IECs or the FDA or foreign equivalent finds deficiencies in our submissions or conduct of our trials.

The results of our clinical trials may not support our product candidate claims and the results of preclinical studies and completed clinical trials are not necessarily predictive of future results.

To date, long-term safety and efficacy have not yet been demonstrated in clinical trials for any of our product candidates. Favorable results in our early studies or trials may not be repeated in later studies or trials as was the case with SYN-010. Even if our clinical trials are initiated and completed as planned, we cannot be certain that the results will support our product candidate claims. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful. Success in Phase 1 and Phase 2 studies of VCN-01 (zabilugene almadenorepvec) in PDAC or retinoblastoma does not ensure success of VCN-01, especially in light of the small number of patients treated in those trials. Success of our predecessor P1A clinical product or positive topline data from our previous SYN-004 (ribaxamase) Phase 1 and Phase 2 clinical trials, does not ensure success of SYN-004 (ribaxamase). Furthermore, the FDA could determine that VCN-01 (zabilugene almadenorepvec) or SYN-004 (ribaxamase) have not demonstrated appropriate safety and thus require additional clinical trials and safety data, despite prior positive clinical trial results. We cannot be sure that the results of later clinical trials would replicate the results of prior clinical trials and preclinical testing nor that they would satisfy the requirements of the FDA or other regulatory agencies. Clinical trials may fail to demonstrate that our product candidates are safe for humans and effective for indicated uses. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. Most product candidates that commence clinical trials are never approved as products. Any such failure could cause us or our sublicensee to abandon a product candidate and might delay development of other product candidates. Preclinical and clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals or commercialization. Any delay in, or termination of, our clinical trials would delay our obtaining FDA approval for the affected product candidate and, ultimately, our ability to commercialize that product candidate.

Difficulties enrolling patients in our clinical trials or delays in enrollment are expected to result in our clinical development activities being delayed or otherwise adversely affected.

Delays in patient enrollment may result in increased costs or may adversely affect timing or outcome of planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our product candidates. This can lead to delays in completion of clinical trials as well as additional expense for recruitment of patients. In addition, any pandemic may result in fewer clinical study personnel being available to conduct clinical testing for patients currently enrolled in our clinical trials.

Patients who are administered our product candidates may experience unexpected side effects or other safety risks that could cause a halt in their clinical development, preclude approval of our product candidates or limit their commercial potential.

Our clinical trials may be suspended at any time for a number of reasons. We may voluntarily suspend or terminate our clinical trials if at any time we believe that they present an unacceptable risk to the clinical trial subjects. In addition, the FDA or other regulatory agencies may order the temporary or permanent discontinuation of our clinical trials at any time if they believe that the clinical trials are not being conducted in accordance with applicable regulatory requirements or that they present an unacceptable safety risk to the clinical trial subjects. For example, the FDA or foreign equivalents could determine that VCN-01 (zabilugene almadenorepvec) or SYN-004 (ribaxamase) has not demonstrated appropriate safety, that adverse events are drug related and require additional clinical trials and safety data, despite positive results from Phase 1 and Phase 2 clinical trials of VCN-01 or our SYN-004 Phase 2b clinical trial.

Administering any product candidate to humans may produce undesirable side effects. These side effects could interrupt, delay or halt clinical trials of our product candidates and could result in the FDA or other regulatory authorities denying further development or approval of our product candidates for any or all targeted indications. Ultimately, some or all of our product candidates may prove to be unsafe for human use. Moreover, we could be subject to significant liability if any volunteer or patient suffers, or appears to suffer, adverse health effects as a result of participating in our clinical trials. Any of these events could prevent us from achieving or maintaining market acceptance of our product candidates and could substantially increase commercialization costs.

It is possible that we may not be able to obtain or maintain orphan drug designation or exclusivity for our drug candidates, which could limit the potential profitability of our product candidates.

Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for the treatment or prevention of rare diseases or conditions with relatively small patient populations as orphan drugs. Under the Orphan Drug Act of 1983, the ("Orphan Drug Act"), the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is defined as a patient population of fewer than 200,000 individuals in the United States. We have received orphan drug designation from both the FDA and EMA for VCN-01 (zabilugene almadenorepvec) for the treatment of retinoblastoma and for the treatment of pancreatic cancer. If a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a seven-year period of marketing exclusivity in the United States, which precludes the FDA from approving another marketing application for the same drug for the same indication during that time period with some exceptions. A similar provision in the European Union allows 10 years of exclusivity in Europe. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that marketing exclusivity is no longer justified. Orphan drug exclusivity may be lost in Europe under certain situations, such as the inability of the holder of the orphan drug designation to produce sufficient quantities of the drug to meet the needs of patients with the rare disease or condition or for certain other reasons.

Although we have been granted orphan drug designation for VCN-01 for the treatment of retinoblastoma and pancreatic cancer, this does not mean FDA will approve the NDA. Even if we obtain FDA approval, we may not be able to obtain or maintain orphan drug exclusivity for VCN-01. We may not be the first to obtain marketing approval of VCN-01 designation for the orphan-designated indication due to the uncertainties associated with developing pharmaceutical products. In addition, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan-designated indication or may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Further, even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties may be approved for the same condition, or the competitive product is otherwise outside the scope of exclusivity. Even after an orphan drug is approved, the FDA can subsequently approve the same drug with the same active moiety for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care or the manufacturer of the product with orphan exclusivity is unable to maintain sufficient product quantity. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process, nor does it prevent competitors from obtaining approval of the same product candidate for indications other than those in which orphan drug designation have been granted.

Fast Track designation by the FDA may not actually lead to a faster development or regulatory review or approval process, and does not assure FDA approval of our product candidate and, even if we obtain FDA approval, we may not receive marketing approval, marketing exclusivity or other expected benefits.

In May 2024, the FDA granted Fast Track designation to VCN-01 (zabilugene almadenorepvec) for the treatment of pancreatic cancer. However, the receipt of such a designation for a product candidate may not result in a faster development process, review or approval compared to drugs considered for approval under conventional regulatory procedures and does not assure that the product will ultimately be approved by the regulatory authority or that approval will be granted within any particular timeframe. As a result, while we have received Fast Track designation for VCN-01 for the treatment of pancreatic cancer, we may not experience a faster development process, review or approval compared to conventional FDA procedures. In addition, the FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program. Fast Track designation alone does not guarantee qualification for the FDA's priority review procedures.

Although we have obtained rare pediatric disease designation for VCN-01 (zabilugene almadenorepvec) ***for the treatment of retinoblastoma, we may not be eligible to receive a priority review voucher in the event the FDA determines we no longer meet the criteria for designation, revokes the designation or FDA approval of a BLA for VCN-01 for retinoblastoma does not occur prior to September 30, 2029.***

The FDA grants rare pediatric disease designation for rare diseases (fewer than 200,000 affected persons in the United States) that are serious and life-threatening and primarily affect children ages 18 years or younger. The sponsor of an application for a rare pediatric disease drug product may be eligible for a voucher that can be used or sold to obtain a priority review for a subsequent application submitted under section 505(b)(1) of the FDCA or section 351 of the PHS Act. Legislative authorization for the rare pediatric disease priority review voucher (PRV) program was most recently authorized by Congress through September 30, 2029.

We received rare pediatric disease designation from the FDA for VCN-01 (zabilugene almadenorepvec) on July 30, 2024. Vouchers for rare pediatric disease drugs are awarded for qualifying applications when the drug receives approval. Although VCN-01 has received rare pediatric disease designation for the treatment of retinoblastoma, VCN-01 may not receive a PRV for a number of reasons: VCN-01 may not receive approval for retinoblastoma prior to the required deadline; VCN-01 may receive approval in adults, but not pediatric patients; VCN-01 may not meet the eligibility requirements for a priority voucher at the time we seek approval for VCN-01. Finally, a rare pediatric disease designation does not necessarily lead to faster development or regulatory review of the product or increase the likelihood that it will receive marketing approval. The failure to maintain rare pediatric disease designation for VCN-01 or if FDA approval does not occur prior to the required deadline could result in the inability to receive a priority review voucher which could adversely affect our business, financial condition and results of operations.

Our product candidates, if approved for sale, may not gain acceptance among physicians, patients and the medical community, thereby limiting our potential to generate revenues.

If one of our product candidates is approved for commercial sale by the FDA or other regulatory authorities, the degree of market acceptance of any approved product by physicians, healthcare professionals and third-party payors and our profitability and growth will depend on a number of factors, including:

- demonstration of safety and efficacy;
- changes in the practice guidelines and the standard of care for the targeted indication;
- relative convenience and ease of administration;
- the prevalence and severity of any adverse side effects;
- budget impact of adoption of our product on relevant drug formularies;
- the availability, cost and potential advantages of alternative treatments, including less expensive generic drugs;
- pricing, reimbursement and cost effectiveness, which may be subject to regulatory control;
- effectiveness of our or any of our partners' sales and marketing strategies;
- the product labeling or product insert required by the FDA or regulatory authority in other countries; and
- the availability of adequate third-party insurance coverage or reimbursement.

If any product candidate that we develop is not as beneficial as, or is perceived as not being as beneficial as, the current standard of care or otherwise does not provide patient benefit, that product candidate, if approved for commercial sale by the FDA or other regulatory authorities, likely will not achieve market acceptance. Our ability to effectively promote and sell any approved products will also depend on pricing and cost-effectiveness, including our ability to produce a product at a competitive price and our ability to obtain sufficient third-party coverage or reimbursement. If any product candidate is approved but does not achieve an adequate level of acceptance by physicians, patients and third-party payors, our ability to generate revenues from that product would be substantially reduced. In addition, our efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources, may be constrained by FDA rules and policies on product promotion, and may never be successful.

We depend on third parties, including researchers and sublicensees, who are not under our control. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to seek or obtain regulatory approval for or commercialize our product candidates.

We depend on independent investigators and scientific collaborators, such as universities and medical institutions or private physician scientists, to advise us and to conduct our preclinical and clinical trials under agreements with us. These collaborators are not our employees and we cannot control the amount or timing of resources that they devote to our programs or the timing of their procurement of clinical-trial data or their compliance with applicable regulatory guidelines. Should any of these scientific inventors/advisors or those of our sublicensee become disabled or die unexpectedly, or should they fail to comply with applicable regulatory guidelines, we or our sublicensee may be forced to scale back or terminate development of that program. They may not assign as great a priority to our programs or pursue them as diligently as we would if we were undertaking those programs ourselves. Failing to devote sufficient time and resources to our drug-development programs, or substandard performance and failure to comply with regulatory guidelines, could result in delay of any FDA applications and our commercialization of the drug candidate involved.

These collaborators may also have relationships with other commercial entities, some of which may compete with us. Our collaborators assisting our competitors could harm our competitive position.

We have in the past, and expect to have in the future, agreements with third-party CROs under which we have delegated to the CROs the responsibility to coordinate and monitor the conduct of our VCN-01 (zabilugene almadenorepvec), SYN-004 (ribaxamase) and SYN-020 (prior to entering into the Rasayana License Agreement) clinical trials and to manage data for our clinical programs. We also rely upon CROs to monitor and manage data for our clinical programs, as well as the execution of future nonclinical studies. We expect to control only certain aspects of our CROs' activities. Nevertheless, we will be responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on the CROs does not relieve us of our regulatory responsibilities.

Our Phase 1b/2a clinical trial of SYN-004, and Phase 1 and Phase 2 clinical trials for VCN-01 are being conducted by clinical sites over which we have little direct control. We, our CROs and our clinical sites are required to comply with current Good Clinical Practices, or cGCPs, regulations and guidelines issued by the FDA and by similar governmental authorities in other countries where we are conducting clinical trials. We have an ongoing obligation to monitor the activities conducted by our CROs and at our clinical sites to confirm compliance with these requirements. In the future, if we, our CROs or our clinical sites fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA may require us to perform additional clinical trials before approving our marketing applications. In addition, our clinical trials must be conducted with product produced under cGMP regulations and will require a large number of test subjects. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. Our CROs are not our employees, and we do not control whether or not they devote sufficient time and resources to our future clinical and nonclinical programs. These CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials, or other drug development activities which could harm our competitive position. We face the risk of potential unauthorized disclosure or misappropriation of our intellectual property by CROs, which may reduce our trade secret protection and allow our potential competitors to access and exploit our proprietary technology. If our CROs or investigator-sponsored clinical sites do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase, and our ability to generate revenue could be delayed.

If our relationship with these CROs terminate, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. Switching or adding additional CROs involves substantial cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we intend to carefully manage our relationships with our CROs, there can be no assurance that it will not encounter challenges or delays in the future or that these delays or challenges will not have an adverse impact on our business, financial condition and prospects.

We currently have no marketing, sales or distribution organization and have no experience in marketing products as a company. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, we may not be able to generate product revenue.

We currently have no marketing, sales or distribution capabilities and have no experience in marketing products. We may develop an in-house marketing organization and sales force, which will require significant capital expenditures, management resources and time. We will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel.

If we are unable to or decide not to, establish internal sales, marketing and distribution capabilities, we will pursue collaborative arrangements regarding the sales and marketing of our products; however, there can be no assurance that we will be able to establish or maintain such collaborative arrangements. Any revenue we receive will depend upon the efforts of such third parties, which may not be successful. We may have little or no control over the marketing and sales efforts of such third parties and our revenue from product sales may be lower than if we had commercialized our product candidates ourselves. We also face competition in our search for third parties to assist us with the sales and marketing efforts of our product candidates.

There can be no assurance that we will be able to develop in-house sales and distribution capabilities or establish or maintain relationships with third-party collaborators to commercialize any product in the United States or overseas.

Reimbursement may not be available for our product candidates, which would impede sales.

Market acceptance and sales of our product candidates may depend in part on coverage and reimbursement policies from third-party payors, such as government insurance programs, including Medicare and Medicaid, private health insurers, health maintenance organizations and other health care related organizations, who are increasingly challenging the price of medical products and services. Accordingly, there is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. Adoption of any drug by the medical community may be limited if third-party payers will not offer adequate coverage. In the United States, the principal decisions about reimbursement for new products are typically made by CMS. Private payors tend to follow CMS to a substantial degree. However, no uniform or consistent policy of coverage and reimbursement for drug products exists among third-party payors. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor as well as from state to state. Consequently, the coverage determination process is often a time-consuming and costly process that must be played out across many jurisdictions and different entities. Further, a payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Furthermore, coverage policies and third-party reimbursement rates may change at any time. Decisions about formulary coverage as well as levels at which government authorities and third-party payers, such as private health insurers and health maintenance organizations, reimburse patients for the price they pay for our products as well as levels at which these payors pay directly for our products, where applicable, could affect whether we are able to commercialize these products. We cannot be sure that reimbursement will be available for any of our product candidates. If approved. Even if favorable coverage and reimbursement status is attained for one or more of our product candidates for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future. Also, we cannot be sure that coverage or reimbursement amounts will not reduce the demand for, or the price of, our products. If coverage and reimbursement are not available or are available only at limited levels, we may not be able to commercialize our product candidates that we develop and that may be approved. Thus, even if we succeed in bringing a product to market, it may not be considered medically necessary or cost-effective, and the amount reimbursed for any products may be insufficient to allow us to sell our products on a competitive basis.

In recent years, officials have made numerous proposals to change the health care system in the United States. These proposals include measures that would limit or prohibit payments for certain medical treatments or subject the pricing of drugs to government control. These proposed legislative and/or regulatory changes may negatively impact the reimbursement for our products, following approval. The availability of numerous generic treatments may also substantially reduce the likelihood of reimbursement for our future products. In addition, in many foreign countries, particularly the countries of the European Union, the pricing of prescription drugs is subject to government control. If our products are or become subject to government regulation that limits or prohibits payment for our products,

or that subjects the price of our products to governmental control, we may not be able to generate revenue, attain profitability or commercialize our products.

As a result of legislative proposals and the trend towards managed health care in the United States, third-party payors are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement of new drugs. They may also impose strict prior authorization requirements and/or refuse to provide any coverage of uses of approved products for medical indications other than those for which the FDA or foreign equivalent has granted market approvals. As a result, significant uncertainty exists as to whether and how much third-party payors will reimburse patients for their use of newly-approved drugs, which in turn will put pressure on the pricing of drugs. The downward pressure on healthcare costs in general, and prescription drugs in particular, has and is expected to continue to increase in the future.

Healthcare reform measures could hinder or prevent our product candidates' commercial success.

The U.S. government and other governments have shown significant interest in pursuing continued healthcare reform. Any government-adopted reform measures could adversely impact the pricing of healthcare products and services in the United States or internationally and the amount of reimbursement available from governmental agencies or other third-party payors. Changes in applicable laws, rules, and regulations or the interpretation of existing laws, rules, and regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of its business. The continuing efforts of the U.S. and foreign governments, insurance companies, managed care organizations and other payors of health care services to contain or reduce health care costs may adversely affect our ability to set prices for our products which we believe are fair, and our ability to generate revenues and achieve and maintain profitability.

In August 2022, the Inflation Reduction Act ("IRA") was enacted, which, among other things, requires the U.S. Department of Health and Human Services ("HHS") to directly negotiate the selling price of a statutorily specified number of drugs and biologics each year that CMS reimburses under Medicare Part B and Part D. The negotiated price may not exceed a statutory ceiling price. Only high-expenditure single-source biologics that have been approved for at least 11 years (seven years for single-source drugs) are eligible to be selected by CMS for negotiation, with the negotiated price taking effect two years after the selection year. For 2026, the first year in which negotiated prices become effective, CMS selected 10 high-cost Medicare Part D products in 2023, negotiations began in 2024, and the negotiated maximum fair price for each product has been announced. In addition, CMS has selected and announced the negotiated maximum fair price for 15 additional Medicare Part D drugs which will become effective in 2027. For 2028, CMS has selected an additional 15 drugs, comprised of drugs covered under Medicare Part D and, for the first time, drugs payable under Medicare Part B. For 2029 and subsequent years, 20 Part B or D drugs will be selected. The negotiated prices have represented, and will continue to represent, a significant discount from average prices to wholesalers and direct purchasers. The IRA also imposes rebates on Medicare Part B and Part D drugs whose prices have increased at a rate greater than the rate of inflation, and in 2024, CMS finalized regulations for the Medicare Part B and Part D inflation rebates. The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. Manufacturers that fail to comply with the IRA may be subject to various penalties, including civil monetary penalties. These provisions have been, and may continue to be, subject to legal challenges. Although full economic effect of the IRA on our business and the pharmaceutical industry in general is unknown at this time, it will likely have a significant impact on the pharmaceutical industry and the pricing of our products and product candidates. Similarly, the adoption of restrictive price controls in new jurisdictions, more restrictive controls in existing jurisdictions or the failure to obtain or maintain timely or adequate pricing could also reduce our profitability. We expect pricing pressures will continue globally.

Additionally, on April 15, 2025, the Trump Administration published Executive Order 14273, "Lowering Drug Prices by Once Again Putting Americans First," which generally directs the federal government to take measures to reduce drug prices. On May 12, 2025, the Trump Administration published Executive Order 14297, "Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients" which generally, among other things, directs the federal government to establish and communicate most-favored-nation price targets to pharmaceutical manufacturers to bring prices for American patients in line with comparably developed nations. Further, the Executive Order directs the federal government to support regulatory paths to allow direct-to-patient sales for companies that meet these targets. It also states that the administration will take additional aggressive action (for example, examining whether marketing approvals should be modified or rescinded or opening the door for individual drug importation waivers) should manufacturers fail to offer American consumers the most-favored-nation lowest price. It also directs the Secretary of Commerce and the U.S. Trade Representative to "take all necessary and appropriate action to ensure foreign countries are not engaged in any act, policy, or practice that may be unreasonable or discriminatory or that may impair United States national security including by suppressing the price of pharmaceutical products below fair market value in foreign countries." Recently, on December 23, 2025, CMS issued proposed regulations to establish, under the Center for Medicare and Medicaid Innovation, two mandatory Most-Favored-Nation demonstration models under Medicare

Parts B and D, respectively. If these rules or other Most-Favored-Nation pricing rules are finalized, they are likely to reduce prices of at least some drugs in the United States, if they are also sold in comparator countries. Even if we do not market drugs in such countries, we will be indirectly affected if our drugs competed with drugs whose prices were reduced as a result of Most-Favored-Nation pricing initiatives.

In addition, at the state level, legislatures have increasingly passed legislation and implemented regulations similar to those under consideration at the federal level, as well as laws designed to control pharmaceutical and biotherapeutic product pricing, including restrictions on pricing or reimbursement at the state government level, limitations on discounts to patients, marketing cost disclosure and transparency measures, restrictions or other limitations on patient assistance, and, in some cases, policies to encourage importation from other countries (subject to federal approval) and bulk purchasing. Certain states are also pursuing cost containment efforts through Prescription Drug Affordability Boards ("PDABs") and similar entities.

New laws, regulations and judicial decisions, or new interpretations of existing laws, regulations and decisions, that relate to healthcare availability, methods of delivery or payment for products and services, or sales, marketing or pricing, may limit our potential revenue, and we may need to revise our research and development programs. The pricing and reimbursement environment may change in the future and become more challenging due to several reasons, including policies advanced by the current executive administration in the United States, new healthcare legislation or fiscal challenges faced by government health administration authorities. Specifically, in both the United States and some foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the health care system in ways that could affect our ability to sell our products profitably.

If we fail to comply with state and federal healthcare regulatory laws, we could face substantial penalties, damages, fines, disgorgement, exclusion from participation in governmental healthcare programs, and the curtailment of operations, any of which could harm our business.

Although we do not provide healthcare services or submit claims for third party reimbursement, we are subject to healthcare fraud and abuse regulation and enforcement by federal and state governments which could significantly impact our business. The laws that may affect our ability to operate include, but are not limited to:

- the federal anti-kickback statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering, or paying remuneration, directly or indirectly, in cash or in kind, in exchange for or to induce either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service for which payment may be made, in whole or in part, under federal healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of this statute or specific intent to violate it;

- the civil FCA, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other third-party payors that are false or fraudulent; knowingly making using, or causing to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the government; or knowingly making, using, or causing to be made or used, a false record or statement to avoid, decrease or conceal an obligation to pay money to the federal government;

- the criminal FCA, which imposes criminal fines or imprisonment against individuals or entities who make or present a claim to the government knowing such claim to be false, fictitious or fraudulent;

- HIPAA, which created federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- the federal civil monetary penalties statute, which prohibits, among other things, the offering or giving of remuneration to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular supplier of items or services reimbursable by a Federal or state governmental program;

- the federal physician sunshine requirements under the ACA, which require certain manufacturers of drugs, devices, biologics, and medical supplies to report annually to the U.S. Department of Health and Human Services information related to payments and other transfers of value to physicians, other healthcare providers, and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members; and

- state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the device industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; and state laws that require device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures.

Further, the ACA, among other things, amended the intent requirements of the federal anti-kickback statute and certain criminal statutes governing healthcare fraud. A person or entity can now be found guilty of violating the statute without actual knowledge of the statute or specific intent to violate it. In addition, the ACA provided that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. If a government authority were to conclude that we provide improper advice to our customers or encouraged the submission of false claims for reimbursement, we could face action against us by government authorities. Any violations of these laws, or any action against us for violation of these laws, even if we successfully defend against it, could result in a material adverse effect on our reputation, business, results of operations and financial condition.

We have entered into consulting and scientific advisory board arrangements with physicians and other healthcare providers. Compensation for some of these arrangements includes the provision of stock options. While we have worked to structure our arrangements to comply with applicable laws, because of the complex and far-reaching nature of these laws, regulatory agencies may view these transactions as prohibited arrangements that must be restructured, or discontinued, or for which we could be subject to other significant penalties. We could be adversely affected if regulatory agencies interpret our financial relationships with providers who influence the ordering of and use our products to be in violation of applicable laws.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry.

Responding to investigations can be time- and resource-consuming and can divert management's attention from the business. Additionally, as a result of these investigations, healthcare providers and entities may have to agree to additional onerous compliance and reporting requirements as part of a consent decree or corporate integrity agreement. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business.

If we obtain approval to commercialize our clinical product candidates outside of the United States, a variety of risks associated with international operations could harm our business.

If our lead clinical product candidate is approved for commercialization, we intend to enter into agreements with third parties to market them in certain jurisdictions outside the United States. We expect that we will be subject to additional risks related to international operations or entering into international business relationships, including:

- different regulatory requirements for drug approvals and rules governing drug commercialization in foreign countries;
- reduced protection for intellectual property rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign reimbursement, pricing and insurance regimes;
- foreign taxes;

- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential noncompliance with the U.S. Foreign Corrupt Practices Act of 1977, as amended, the U.K. Bribery Act 2010 and similar anti-bribery and anticorruption laws in other jurisdictions;
- product shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

We have no prior experience in these areas. In addition, there are complex regulatory, tax, labor and other legal requirements imposed by both the European Union and many of the individual countries in Europe with which we will need to comply.

If product liability lawsuits are successfully brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

We face an inherent risk of product liability lawsuits related to the testing of our product candidates and will face an even greater risk if we sell our product candidates commercially. Currently, we are not aware of any anticipated product liability claims with respect to our product candidates. In the future, an individual may bring a liability claim against us if one of our product candidates causes, or merely appears to have caused, an injury. If we cannot successfully defend ourselves against the product liability claim, we may incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for our product candidates;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs of related litigation;
- initiation of investigations by regulators;
- substantial monetary awards to patients or other claimants;
- distraction of management's attention from our primary business;
- product recalls;
- loss of revenue; and
- the inability to commercialize our product candidates.

We have clinical trial liability insurance. We intend to expand our insurance coverage to include the sale of commercial products if marketing approval is obtained for our product candidates. Our current insurance coverage may prove insufficient to cover any liability claims brought against us. In addition, because of the increasing costs of insurance coverage, we may not be able to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy liabilities that may arise.

We and our subsidiaries are subject to U.S. and foreign tax laws, and changes to such tax laws or differing interpretation of those laws by the relevant governmental authorities could adversely affect our business and operating results.

The U.S. Congress, the Organization for Economic Co-operation and Development and other government agencies in jurisdictions where we do business have had an extended focus on issues related to the taxation of multinational corporations. One example is in the

area of "base erosion and profit shifting," where payments are made between affiliates from a jurisdiction with high tax rates to a jurisdiction with lower tax rates. Additionally, changes proposed by the current U.S. administration, including significant tax reform, could significantly change the U.S. federal income tax rules and regulations applicable to us and our subsidiaries, although the prospect of tax reform, and the nature of any such reform, remains highly uncertain. Thus, the tax laws in the United States, Spain and other countries in which we and our subsidiaries do business could change on a prospective or retroactive basis, and any such changes could adversely affect us.

In addition, the tax laws and regulations in the United States, the EU and the various other jurisdictions in which we and our subsidiaries operate or may in the future operate are inherently complex, and we and our subsidiaries will be obligated to make judgments and interpretations about the application of these laws and regulations to us and our subsidiaries and our and their operations and businesses. The interpretation and application of these laws and regulations could be challenged by the relevant governmental authorities, which could result in material administrative or judicial procedures, actions or sanctions.

INTELLECTUAL PROPERTY RISKS

We rely on patents, patent applications, trade secrets and various regulatory exclusivities to protect some of our product candidates and our ability to compete may be limited or eliminated if we are not able to protect our products.

The patent positions of pharmaceutical companies are uncertain and may involve complex legal and factual questions. The issuance, scope, validity, enforceability, and commercial value of our current or future patent rights are highly uncertain. We cannot be sure that patent coverage will issue, or will be maintained, to protect our products, in some or all relevant jurisdictions. Our patents may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Even if patents do successfully issue and even if such patents cover our product candidates and extend for a commercially relevant time, third parties may initiate invalidity, non-infringement, opposition, interference, re-examination, post-grant review, inter partes review, nullification, or derivation actions in court or before patent offices, or similar proceedings challenging the validity, inventorship, ownership, enforceability, or scope of such patents, which may result in the patent claims being narrowed, invalidated, or held unenforceable or circumvented. Additionally, some countries, including China and India, have compulsory licensing laws under which we may be compelled to grant licenses to others.

We may incur significant expenses in protecting our intellectual property and defending or assessing claims with respect to intellectual property owned by others. Any patent or other infringement litigation by or against us could cause us to incur significant expenses and divert the attention of our management. Even for our issued patents, we do not have a guarantee of patent term restoration and marketing exclusivity of the ingredients for our drugs under the Hatch-Waxman Amendments, even if we are granted FDA approval of our products.

Furthermore, others may file patent applications or obtain patents on similar technologies or compounds that compete with our products. We cannot predict how broad the claims in any such patents or applications will be, and whether they will be allowed. Once claims have been issued, we cannot predict how they will be construed or enforced. We may infringe intellectual property rights of others without being aware of it. If another party claims we are infringing their technology, we could have to defend an expensive and time consuming lawsuit, pay a large sum if we are found to be infringing, or be prohibited from selling or licensing our products unless we obtain a license or redesign our product, which may not be possible.

We also rely on trade secrets and proprietary know-how to develop and maintain our competitive position. We cannot be sure our measures to protect our trade secrets will be sufficient. Some of our current or former employees, consultants, scientific advisors, current or prospective corporate collaborators, may unintentionally or willfully disclose our confidential information to competitors or use our proprietary technology for their own benefit. Furthermore, enforcing a claim alleging the infringement of our trade secrets would be expensive and difficult to prove, making the outcome uncertain. Our competitors may also independently develop similar knowledge, methods, and know-how or gain access to our proprietary information through some other means.

We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights, as well as costs associated with lawsuits.

If any other person files patent applications, or is issued patents, claiming technology also claimed by us in pending applications, we may be required to participate in interference proceedings in the U.S. Patent and Trademark Office to determine priority of invention. We, or our licensors, may also need to participate in interference proceedings involving our issued patents and pending applications of another entity. The European Patent Office and some national patent authorities have formal patent opposition processes where the

validity of issued patents may be challenged. If a patent opposition is filed, we, or our licensors, may also need to participate in opposition proceedings involving our issued patents.

The intellectual property environment in the oncolytic viruses field is particularly complex, constantly evolving and highly fragmented. We have not conducted freedom-to-use patent searches on all aspects of our product candidates or potential product candidates, and we may be unaware of relevant patents and patent applications of third parties. In addition, the freedom-to-use patent searches that have been conducted may not have identified all relevant issued patents or pending patents. We cannot provide assurance that our proposed products in this area will not ultimately be held to infringe one or more valid claims owned by third parties which may exist or come to exist in the future or that in such case we will be able to obtain a license from such parties on acceptable terms.

We cannot guarantee that the practice of our technologies will not conflict with the rights of others. In some foreign jurisdictions, we could become involved in opposition proceedings, either by opposing the validity of another's foreign patent or by persons opposing the validity of our foreign patents.

We may also face frivolous litigation or lawsuits from various competitors or from litigious securities attorneys. The cost to us of any litigation or other proceeding relating to these areas, even if deemed frivolous or resolved in our favor, could be substantial and could distract management from our business. Uncertainties resulting from initiation and continuation of any litigation could have a material adverse effect on our ability to continue our operations.

If we infringe the rights of others, we could be prevented from selling products or forced to pay damages.

If our products, methods, processes, and other technologies are found to infringe the proprietary rights of other parties, we could be required to pay damages, or we may be required to cease using the technology or to license rights from the prevailing party. Any prevailing party may be unwilling to offer us a license on commercially acceptable terms.

We enjoy restricted geographical protection with respect to certain patents.

Patents are of national or regional effect. While we will try to protect our technologies, products and product candidates with intellectual property rights such as patents throughout the world in major markets, the process of obtaining patents is time-consuming, expensive, and sometimes unpredictable in other countries. We may not pursue or obtain patent protection in all markets. Filing, prosecuting, and defending patents on all of our research programs and product candidates in all countries throughout the world would be prohibitively expensive, and, therefore, the scope and strength of our intellectual property rights will vary from jurisdiction to jurisdiction.

We may become subject to claims challenging inventorship or ownership of our patents and other intellectual property.

We generally enter into confidentiality and intellectual property assignment agreements with our employees, consultants, and contractors. These agreements generally provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, those agreements may not be honored and may not effectively assign intellectual property rights to us. Moreover, there may be some circumstances where we are unable to negotiate for such ownership rights. Disputes regarding ownership or inventorship of intellectual property can also arise in other contexts, such as collaborations and sponsored research. If we are subject to a dispute challenging our rights in or to patents or other intellectual property, such a dispute could be expensive and time consuming. If we were unsuccessful, we could lose valuable rights in intellectual property that we regard as our own.

RISKS RELATING TO OUR SECURITIES

We cannot assure you that our Common Stock will be liquid or that it will remain listed on the NYSE American.

Our Common Stock is listed on the NYSE American. The NYSE American's listing standards generally mandate that we meet certain requirements relating to stockholders' equity, stock price, market capitalization, aggregate market value of publicly held shares and distribution requirements.

We cannot assure you that we will be able to maintain the continued listing standards of the NYSE American. The NYSE American requires companies to meet certain continued listing criteria including a minimum stockholders' equity of $6.0 million if an issuer has sustained losses from continuing operations and/or net losses in its five most recent years, as outlined in the NYSE American Company Guide and trading of the stock above $0.10 per share. The NYSE American Company Guide also states that the NYSE normally will not consider removing from listing securities of an issuer if it is in compliance with all of the following: a total value of market

capitalization of at least $50.0 million; 1,100,000 publicly-held shares; a market value of publicly held shares of at least $15.0 million; and 400 round lot shareholders. In addition, the NYSE American has informed us that it can commence delisting proceedings and immediately suspend trading in the event that our Common Stock trades at levels viewed to be abnormally low and no longer suitable for listing pursuant to Section 1003(f)(v) of the NYSE American Company Guide. Currently, the NYSE American views trading at or below a price of $0.10 to be abnormally low. New reverse stock split rules implemented by the NYSE American in January 2025 limit the circumstances under which reverse stock splits can be used in order to cure low trading price deficiencies, including the immediate suspension and delisting of any company that has effected one or more reverse stock splits over the prior two year period with a cumulative ratio of 200 shares or more to one. Based on these rules, due to the reverse stock split effected in August 2024, we would be limited in effecting a reverse stock split to cure a low price deficiency.

As stated above, in the event that we were to fail to meet the requirements of NYSE American per share price requirement the NYSE American could commence delisting proceedings and immediately suspend trading of our Common Stock on the NYSE American or if we fail to meet other requirements such as the stockholders' equity requirement and we could not timely cure such deficiency, our listing could become subject to NYSE American continued listing evaluation and follow-up procedures, which could result in delisting procedures.

We previously received notification from the NYSE American citing failure to comply with the minimum stockholders' equity continued listing standard as set forth in Part 10, Section 1003 of the Company Guide. Although in the past we have been able to cure previously cited deficiencies, there can be no assurance that we will continue to meet the NYSE American continued listing requirements.

In addition, in the future we may not be able to ensure that our Common Stock trades at levels not viewed to be abnormally low and no longer suitable for listing or maintain minimum stockholders' equity and/or issue additional equity securities in exchange for cash or other assets, if available, to maintain certain minimum stockholders' equity required by the NYSE American. If we are delisted from the NYSE American then our Common Stock will trade, if at all, only on the over-the-counter market, such as the OTC Bulletin Board securities market, and then only if one or more registered broker-dealer market makers comply with quotation requirements. In addition, delisting of our Common Stock could depress our stock price, substantially limit liquidity of our Common Stock and materially adversely affect our ability to raise capital on terms acceptable to us, or at all. Delisting from the NYSE American could also have other negative results, including the potential loss of confidence by suppliers and employees, the loss of institutional investor interest and fewer business development opportunities. We cannot assure you that our Common Stock will be liquid or that it will remain listed on the NYSE American. A failure to regain compliance with the NYSE American stockholders' equity requirements or failure to continue to meet the other listing requirements could result in a de-listing of our Common Stock.

The market price of our Common Stock has been and may continue to be volatile and adversely affected by various factors.

Our stock price has fluctuated in the past, has been volatile and may be volatile in the future. We may incur rapid and substantial decreases in our stock price in the foreseeable future that are unrelated to our operating performance or prospects. The stock market in general and the market for biotechnology and pharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may experience losses on their investment in our Common Stock. The market price of our Common Stock could fluctuate significantly in response to various factors and events, including:

- investor reaction to our business strategy;
- the success of competitive products or technologies;
- our continued compliance with the listing standards of the NYSE American;
- regulatory or legal developments in the United States and other countries, especially changes in laws or regulations applicable to our products;
- results of our clinical trials;
- actions taken by regulatory agencies with respect to our products, clinical studies, manufacturing process or sales and marketing terms;
- variations in our financial results or those of companies that are perceived to be similar to us;

- the success of our efforts to acquire or in-license additional products or product candidates;
- developments concerning our collaborations or partners;
- developments or disputes concerning patents or other proprietary rights, litigation matters and our ability to obtain patent protection for our products;
- our ability or inability to raise additional capital and the terms on which we raise it;
- declines in the market prices of stocks generally;
- trading volume of our Common Stock;
- sales of our Common Stock by us or our stockholders;
- general economic, industry and market conditions; and
- other events or factors, including those resulting from such events, or the prospect of such events, including war, terrorism and other international conflicts, which restrict a wide range of trade and financial dealings, public health issues including health epidemics or pandemics, and natural disasters such as fire, hurricanes, earthquakes, tornados or other adverse weather and climate conditions, whether occurring in the United States or elsewhere, could disrupt our operations, disrupt the operations of our suppliers or result in political or economic instability.

These broad market and industry factors may seriously harm the market price of our Common Stock, regardless of our operating performance. Further, recent increases are significantly inconsistent with any improvements in actual or expected operating performance, financial condition or other indicators of value. Since the stock price of our Common Stock has fluctuated in the past, has been recently volatile and may be volatile in the future, investors in our Common Stock could incur substantial losses. In the past, following periods of volatility in the market, securities class-action litigation has often been instituted against companies. Such litigation, if instituted against us, could result in substantial costs and diversion of management's attention and resources, which could materially and adversely affect our business, financial condition, results of operations and growth prospects. There can be no guarantee that our stock price will remain at current prices or that future sales of our Common Stock will not be at prices lower than those sold to investors.

Additionally, recently, securities of certain companies have experienced significant and extreme volatility in stock price due to short sellers of shares of Common Stock, known as a "short squeeze." These short squeezes have caused extreme volatility in those companies and in the market and have led the price per share of those companies to trade at a significantly inflated rate that is disconnected from the underlying value of the company. Many investors who have purchased shares in those companies at an inflated rate face the risk of losing a significant portion of their original investment as the price per share has declined steadily as interest in those stocks have abated. While we have no reason to believe our shares would be the target of a short squeeze, there can be no assurance that we won't be in the future, and you may lose a significant portion or all of your investment if you purchase our shares at a rate that is significantly disconnected from our underlying value.

Our Charter and bylaws and Nevada law may have anti-takeover effects that could discourage, delay or prevent a change in control, which may cause our stock price to decline.

Our Charter, our second amended and restated bylaws and Nevada law could make it more difficult for a third party to acquire us, even if closing such a transaction would be beneficial to our stockholders. The Board of Directors could authorize the issuance of an additional series of preferred stock that would grant holders preferred rights to our assets upon liquidation, special voting rights, the right to receive dividends before dividends would be declared to common stockholders, and the right to the redemption of such shares, possibly together with a premium, prior to the redemption of the Common Stock. To the extent that we do issue additional preferred stock, the rights of holders of Common Stock could be impaired thereby, including without limitation, with respect to liquidation.

Provisions of our Charter, and our second amended and restated bylaws may also prevent or frustrate attempts by our stockholders to replace or remove our management. In particular, our Charter, and second amended and restated bylaws, among other things:

- provide the board of directors with the ability to alter the bylaws without stockholder approval; and

- provide that vacancies on the board of directors may be filled by a majority of directors in office, although less than a quorum.

We do not intend to pay dividends in the foreseeable future on our Common Stock.

We have never paid cash dividends on our Common Stock. We currently intend to retain our future earnings, if any, to finance the operation and growth of our business and currently do not plan to pay any cash dividends in the foreseeable future. If we do not pay dividends, our Common Stock may be less valuable because a return on your investment will only occur if the market price of our Common Stock price appreciates.

Resales of our Common Stock in the public market by our stockholders may cause the market price of our common stock to fall.

We may issue shares of Common Stock or securities convertible into or exercisable for shares of Common Stock from time to time in connection with future offerings. Any issuance from time to time of new shares of our Common Stock, or our ability to issue shares of Common Stock in future offerings, could result in resales of our Common Stock by our current stockholders concerned about the potential dilution of their holdings. In turn, these resales could have the effect of depressing the market price for our Common Stock.

The shares of Common Stock offered under our current ATM Sales Agreement may be sold in "at the market" offerings, and investors who buy shares at different times will likely pay different prices.

Investors who purchase shares that are sold under our current ATM Sales Agreement at different times will likely pay different prices, and so may experience different outcomes in their investment results. We will have discretion, subject to market demand, to vary the timing, prices, and numbers of shares sold, and there is no minimum or maximum sales price.

Investors may experience declines in the value of their shares as a result of share sales made at prices lower than the prices they paid.

Item 1B. ***Unresolved Staff Comments.***

None.

Item 1C. ***Cybersecurity***

We maintain a cyber risk management program designed to identify, assess, manage, mitigate, and respond to cybersecurity threats.

Theriva has not, to date, been subject to any cybersecurity incidents resulting in a material adverse effect on the Company; however, future cyber incidents may occur and the Company has implemented processes to manage, mitigate, and respond to cybersecurity threats. We maintain policies and controls over areas such as information security, access on/offboarding, and access and account management, to help govern the processes put in place by management designed to protect our information technology ("IT") assets, data, and services from threats and vulnerabilities. We partner with third-party IT providers leveraging third-party technology and expertise. These partners, including consultants and other third-party service providers, are a key part of Theriva's cybersecurity risk management strategy and infrastructure and provide services including, maintenance of an IT assets inventory, periodic vulnerability scanning, identity access management controls including restricted access of privileged accounts, network integrity safeguarded by employing web-based software, including endpoint protection, endpoint detection and response, and remote monitoring management on all devices, industry-standard encryption protocols, critical data backups, infrastructure maintenance, incident response, and cyber risk advisory, assessment and remediation.

As part of its review of the adequacy of our system of internal controls over financial reporting and disclosure controls and procedures, management and the Audit Committee oversee cybersecurity risk exposures and the steps taken by management to monitor and mitigate cybersecurity risks. Theriva's management team is responsible for oversight and administration of cybersecurity risk management strategies, and for informing the Board and other relevant stakeholders regarding the prevention, detection, mitigation, and remediation of cybersecurity incidents. In addition, cybersecurity risks are reviewed by our Board of Directors at least annually, as part of the Company's corporate risk oversight processes.

We face risks from cybersecurity threats that could have a material adverse effect on our business, financial condition, results of operations, cash flows or reputation. Theriva acknowledges that the risk of cyber incident is prevalent in the current threat landscape and that a future cyber incident may occur in the normal course of its business. We proactively seek to detect and investigate unauthorized attempts and attacks against our IT assets, data, and services, and to prevent their occurrence and recurrence where practicable through changes or updates to internal processes and tools and changes or updates to service delivery; however, potential vulnerabilities to known or unknown threats will remain. Further, there is increasing regulation regarding responses to cybersecurity incidents, including reporting to regulators, investors, and additional stakeholders, which could subject us to additional liability and reputational harm. In response to such risks, we have implemented initiatives such as implementation of the cybersecurity risk assessment process and development of an incident response plan. See Item 1A. "Risk Factors" for more information on cybersecurity risks.

Item 2. ***Properties.***

Our corporate headquarters are located at 9605 Medical Center Drive, Suite 270, Rockville, Maryland, where we occupy approximately 10,363 square feet of office space under a lease agreement expiring December 31, 2027, with monthly rent of $28,001. Our Spanish subsidiary Theriva Biologics S.L. (formerly VCN Biosciences S.L.) currently leases approximately 8,611 square feet of office and laboratory space office space from Grifols in Parets de Vallès, Barcelona, Spain with a rent of $27,054 per month. This lease was executed for an initial term beginning in January 2023 until October 2026, with an option to renew for an additional five years.

We do not own any real property. We believe that we have adequate space for our anticipated needs and that suitable additional space will be available at commercially reasonable prices as needed.

Item 3. ***Legal Proceedings.***

From time to time we may become involved in legal proceedings or be subject to claims arising in the ordinary course of our business. We are not presently a party to any legal proceedings that, if determined adversely to us, would individually or taken together have a material adverse effect on our business, operating results, financial condition or cash flows. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

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 has traded on the NYSE American under the symbol "TOVX" since October 13, 2022. Prior to October 13, 2022 our Common Stock traded under the symbol "SYN" beginning February 16, 2012. Prior to February 16, 2012, our Common Stock traded under the symbol "AEN" beginning October 16, 2008. The last price of our Common Stock as reported on the NYSE American on March 10, 2026 *was $0.178 per* share.

Dividend Policy

We have never paid or declared any cash dividends on our Common Stock to date, and do not anticipate paying such cash dividends on our Common Stock in the foreseeable future. Whether we declare and pay dividends is determined by our Board of Directors at their discretion, subject to certain limitations imposed under Nevada corporate law. The timing, amount and form of dividends, if any, will depend on, among other things, our results of operations, financial condition, cash requirements and other factors deemed relevant by our Board of Directors.

The Series A Preferred Stock, none of which remains outstanding, ranked senior to the shares of our Common Stock and shares of our Series B Preferred Stock with respect to dividend rights and holders of shares of our Series A Preferred Stock, were entitled to a cumulative dividend at the rate of 2.0% per annum, payable quarterly in arrears, as set forth in the Certificate of Designation of Series A Convertible Preferred Stock. The Series B Preferred Stock, Series C Preferred Stock and Series D Preferred Stock, none of which remains outstanding, were entitled to receive dividends on an as-if-converted-to-common-stock basis to and in the same form as dividends actually paid on shares of the Common Stock when, as and if such dividends are paid on shares of the Common Stock.

Holders

As of March 10, 2026, we had approximately 52 stockholders of record of our Common Stock. This number does not include stockholders for whom shares are held in a "nominee" or "street" name.

Stock Performance Graph

The Company is a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and is not required to provide the information required under this item.

Equity Compensation Plan Information

See Part III–Item 12 under the heading "Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters—Equity Compensation Plan Information" of this Annual Report for equity compensation plan information.

Recent Sales of Unregistered Securities

We did not sell any equity securities during the year ended December 31, 2025 in transactions that were not registered under the Securities Act, other than as previously disclosed in a Current Report on Form 8-K or our Quarterly Reports on Form 10-Q filed with the SEC.

Issuer Purchases of Equity Securities

We did not repurchase any equity securities during the fourth quarter or year ended December 31, 2025.

Item 6. [Reserved]

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

The following discussion of our financial condition and results of operations should be read in conjunction with our audited financial statements and notes thereto for the years ended December 31, 2025 and 2024 included elsewhere in this Annual Report. In addition to historical information, the following discussion contains certain forward-looking statements that involve risks, uncertainties and assumptions. Where possible, we have tried to identify these forward-looking statements by using words such as "anticipate," "believe," "intends," or similar expressions. Our actual results could differ materially from those expressed or implied by the forward-looking statements due to important factors and risks including, but not limited to, those set forth under "Risk Factors" in Part I, Item 1A of this Annual Report.

Overview

We are a diversified clinical-stage company developing therapeutics designed to treat cancer and related diseases in areas of high unmet need. As a result of the Acquisition in March 2022, we transitioned our strategic focus to oncology through the development of VCN's new oncolytic adenovirus platform designed for intravenous and intravitreal delivery to trigger tumor cell death, to improve access of co-administered cancer therapies to the tumor, and to promote a robust and sustained anti-tumor response by the patient's immune system. Our lead product candidate, VCN-01 (zabilugene almadenorepvec), is a clinical stage oncolytic human adenovirus that is modified for tumor-selective replication and to express an enzyme, PH20 hyaluronidase. VCN-01 has been evaluated in a Phase 2b clinical study for the treatment of pancreatic cancer ("VIRAGE"), a Phase 1 clinical study for the treatment of retinoblastoma, as well as various other Phase 1 clinical studies for the treatment of other solid tumors including head and neck squamous cell carcinoma.

Prior to the Acquisition, our focus was on developing therapeutics designed to treat gastrointestinal (GI) diseases which included our clinical development candidates: (1) SYN-004 (ribaxamase) which is designed to degrade certain commonly used intravenous (IV) beta-lactam antibiotics within the GI tract to prevent microbiome damage, thereby preventing overgrowth and infection by pathogenic organisms such as *Clostridioides difficile* infection (CDI) and vancomycin resistant Enterococci (VRE), and reducing the incidence and severity of acute graft-versus-host-disease (aGVHD) in allogeneic hematopoietic cell transplant (HCT) recipients, and (2) SYN-020, a recombinant oral formulation of the enzyme intestinal alkaline phosphatase (IAP) produced under cGMP conditions and intended to treat both local GI and systemic diseases. In February 2026, we entered into the Rasayana License Agreement with Rasayana, pursuant to which we granted Rasayana an exclusive worldwide license with the right to grant sublicenses to research, develop, manufacture and commercialize any Product (as such term is defined in the Rasayana License Agreement), which includes SYN-020, comprising, containing, or covered by the Licensed IP (as such term is defined in the Rasayana License Agreement) and/or devised, developed, or produced using the Licensed IP. Pursuant to the terms of the Rasayana License Agreement, Rasayana will assume all responsibility and costs for the Development and Commercialization of the Products. We believe that this arrangement will provide us with potential to derive value from our SYN-020 asset, without the need for us to continue to invest additional working capital into the further development of the product candidate, thereby allowing us to focus our efforts and expenditures on the development of our oncology assets.

Additionally, as part of our strategic transformation into an oncology focused company, we are exploring value creation options for our SYN-004 asset, including out-licensing or partnering.

Financial Developments

On September 28, 2025, the Board of Directors approved the Plan to resize and restructure our company for purposes of focusing its attention on business development and licensing activities, clinical trial planning, exploratory VCN-01 (zabilugene almadenorepvec) manufacturing scale-up, limited preclinical activities related to VCN-01 and VCN-12 (the first candidate from our VCN-X discovery program), and our interactions with the FDA and the EMA for proposed pivotal clinical trials of VCN-01 in patients with mPDAC and retinoblastoma. Pursuant to the Plan, on September 30, 2025, we implemented a workforce reduction of seven employees or 32% of the then global Company workforce. The goal of this reduction was to direct our resources towards the activities detailed above in the Plan, which we believe will represent our best opportunity for success. We completed the employee reduction immediately and incurred a total of approximately $520,000 in charges in connection with the workforce reduction. These charges consisted primarily of cash severance and benefits over a three-month period, in connection with the workforce reduction. The Plan is expected to save approximately $1.8 million in compensation and benefits annually beginning in 2026, and together with additional anticipated operating cost reductions and capital raised pursuant to the ATM Sales Agreement, we expect that it will extend our cash runway into the first quarter of 2027; however, the current cash will only be sufficient to run certain clinical trials and no assurances can be provided and our cash could differ materially from our expectations based on various factors, many of which are out of our control.

Warrant Inducement

On October 16, 2025, we entered into a warrant inducement agreement (the "Inducement Agreement") with certain holders named therein (the "Holders") of existing Common Stock Purchase Warrants to purchase up to an aggregate of 8,092,280 shares of Common Stock, consisting of (i) Common Stock Purchase Warrants to purchase up to an aggregate of 1,345,000 shares of Common Stock issued on September 27, 2024 (the "September Warrants") and (ii) Common Stock Purchase Warrants to purchase up to an aggregate of 6,747,280 shares of Common Stock issued on May 8, 2025 (the "May Warrants" and, together with the September Warrants, the "Existing Warrants"). Pursuant to the Inducement Agreement, on October 17, 2025, the Holders exercised for cash the Existing Warrants at a reduced exercise price of $0.54 per share and, in consideration therefor, we issued to the Holders new Common Stock Purchase Warrants (the "New Warrants") to purchase an aggregate of 16,184,560 shares of common stock, equal to 200% of the number of shares of common stock underlying the Existing Warrants, at an exercise price of $0.54 per share, which New Warrants are exercisable for a term of five (5) years from the date of the approval from our stockholders of the full exercise of the New Warrants and the issuance of all of the shares of common stock issuable upon the exercise thereof.

We received aggregate gross proceeds of approximately $4.4 million for the exercise of the Existing Warrants, before deducting placement agent fees of $356,000 and other expenses of $72,000 payable by the Company. We expect to use the net proceeds from the Warrant Exercise for working capital. AGP served as our exclusive financial advisor in connection with the warrant exercise and other transactions described in the Inducement Agreement. Pursuant to the terms of an engagement letter, dated October 16, 2025, by and between us and AGP, we agreed to pay to AGP a cash fee equal to 7.0% of the aggregate gross proceeds received from the Holders upon exercise of the Existing Warrants and reimbursement of certain expenses.

2025 Annual Stockholder's Meeting

On August 29, 2025, we held our 2025 Annual Meeting of Stockholders (the "Annual Meeting"). At the Annual Meeting, our stockholders (i) elected Jeffrey J. Kraws, John Monahan, Steven A. Shallcross and Jeffery Wolf as directors; (ii) ratified the appointment of BDO USA P.C. as our independent registered public accounting firm for the year ending December 31, 2025; (iii) approved an amendment ("Amendment No. 2") to our 2020 Stock Incentive Plan (the "2020 Stock Incentive Plan") to (a) increase the number of shares of common stock that we will have authority to grant under the 2020 Stock Incentive Plan from 2,500,000 shares of common stock to 4,500,000 shares of common stock and (iii) approved, on an advisory basis, the compensation of our named executive officers.

Tax Credit Receivable

For the years ended December 31, 2025 and 2024, we recognized a $3.4 million and $3.2 million, respectively, tax credit receivable and a corresponding current and non-current deferred research and development tax credit receivable of $1.7 million and $815,000 for the year ended December, 31 2025 and $1.6 million and $762,000 for the year ended December 31, 2024. We participate in a research and development program sponsored by the Spanish government. The program provides for reimbursement of certain expenses incurred in research and development efforts we conduct in Spain. The reimbursements can be through either tax credits or direct refunds. The program provides for certain limits on the types and amounts of expenses and requires participants to complete a certification and apply for the refund annually. Subsequent to the period in which expenses are incurred, the program requires participants to maintain certain workforce levels and research and development expenditures over a 24-month period. In the quarter ended June 30, 2024, we completed the certification and applied for direct reimbursement, for our qualifying research and development expenses incurred in the year ended December 31, 2023. We received approvals from the Spanish government in September and December 2024. The credit will be amortized as a contra-expense over the two-year period 2025 and 2026. In the quarter ended June 30, 2025, we completed the certification and applied for direct reimbursement, for our qualifying research and development expenses incurred in the year ended December 31, 2024. We received approvals from the Spanish government in December 2024. The credit will be amortized as a contra - expense over the two - year period 2026 and 2027.

At Market Issuance Sales Agreement

On June 20, 2025, we filed a prospectus supplement to our Registration Statement on Form S-3, as amended (File No. 333-279077), which was declared effective by the SEC on September 25, 2024 (the "Registration Statement"), relating to the offer and sale of up to $2,534,352 of shares of our Common Stock, from time to time through or directly to A.G.P./Alliance Global Partners (the "Sales Agent") pursuant to the terms of that certain Amended and Restated At Market Issuance Sales Agreement, dated February 9, 2021, as amended by Amendment No. 1 thereto, dated May 3, 2021, as further amended by Amendment No. 2 thereto, dated May 2, 2024 (the "ATM Sales Agreement"). On October 24, 2025, we filed prospectus supplement no. 2 to the Registration Statement, relating to the offer and sale of up to $4,019,597 of shares of our Common Stock pursuant to the ATM Sales Agreement, and on October 29, 2025, we filed

prospectus supplement no. 3 to the Registration Statement, relating to the offer and sale of up to $2,894,225 of shares of our Common Stock pursuant to the ATM Sales Agreement. Sales of Common Stock, if any, under the prospectus supplements will be made by any method permitted that is deemed an "at the market offering" as defined in Rule 415(a)(4) promulgated under the Securities Act. The Sales Agent is not required to sell any specific amount, but will act as our Sales Agent using commercially reasonable efforts consistent with its normal trading and sales practices. The Sales Agent will be entitled to compensation at a commission rate equal to up to 3.0% of the gross sales price per share of Common Stock sold. During the three months and year ended December 31, 2025, we sold approximately 17,291,307 and 17,998,117 shares of our Common Stock, respectively, pursuant to the ATM Sales Agreement and received net proceeds of approximately $6.5 million and $6.8 million, respectively. During the first quarter of 2026, we sold approximately 10,204,319 shares of our Common Stock pursuant to the ATM Sales Agreement and received net proceeds of approximately $2.3 million.

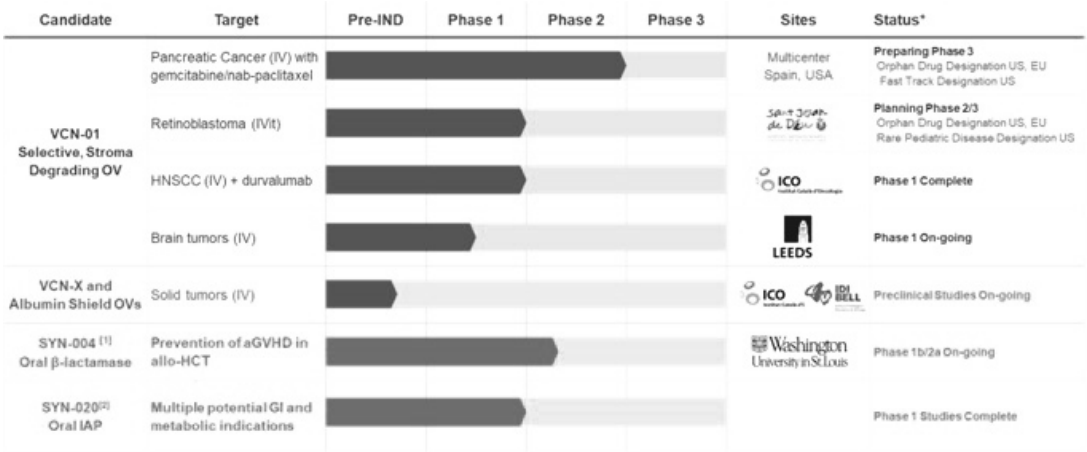
Rasayana License Agreement

On February 17, 2026, we entered into the Rasayana License Agreement with Rasayana, pursuant to which we received an upfront payment of $300,000 from Rasayana. In addition, we are entitled to receive from Rasayana development milestone payments of up to an aggregate of $16.0 million and sales milestone payments of up to an aggregate of $22.0 million upon achievement of certain development and net sales milestones with respect to Products. In addition, during the Royalty Term (as such term is defined in the Rasayana License Agreement), we are entitled to receive tiered royalties ranging from low to mid single digits on net sales of a Product. We will also be entitled to receive a certain percentage of any Sublicense Revenue (as such term is defined in the Rasayana License Agreement) received by Rasayana or its affiliates.

Under the terms and conditions of the Rasayana License Agreement, Rasayana will assume all responsibility and costs for the development and commercialization of the Products. Accordingly, going forward, we do not expect to continue to conduct research and development activities, including conducting further clinical studies, with respect to SYN-020, and do not expect to incur material expenditures in connection therewith.

See the section entitled "*Our Current Collaborations – Rasayana License Agreement*" in Part I Item 1 of this Auual Report on Form 10-K for additional information regarding the Rasayana License Agreement.

Our Current Product Pipeline



Based on management's current beliefs and expectations

allo-HCT allogeneic hematopoietic cell transplant. **CSR** clinical study report. **HNSCC** head and neck squamous cell carcinoma. **IV** intravenous. **IVit** intravitreal. For other abbreviations see the text.

[1]Final Phase 1b/2a study cohort contingent on grant funding or partnership.

[2]Pursuant to the Rasayana License Agreement, commencing February 7, 2026, Rasayana is responsible for all development and commercialization efforts, including all costs related thereto, of SYN-020, and is obligated to use commercially reasonable efforts to meet certain specified development milestones, as more particularly set forth in the Rasayana License Agreement.

Additional products with preclinical proof-of-concept include SYN-006 (carbapenemase) to prevent aGVHD, CDI, and microbiome damage in patients treated with carbapenem antibiotics and SYN-007 (ribaxamase) DR to prevent antibiotic associated diarrhea with oral β-lactam antibiotics.

Critical Accounting Estimates

The preparation of our consolidated financial statements in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") which requires the use of estimates, judgments and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, and the reported amounts of expenses in the periods presented. We believe that the accounting estimates employed are appropriate and resulting balances are reasonable; however, due to inherent uncertainties in making estimates, actual results may differ from the original estimates, requiring adjustments to these balances in future periods.

There are accounting policies, each of which requires significant judgments and estimates on the part of management, that we believe are significant to the presentation of our consolidated financial statements. The most significant accounting estimates relate to valuation of IPR&D and contingent consideration.

IPR&D

IPR&D assets are considered to be indefinite-lived until the completion or abandonment of the associated research and development projects. IPR&D assets represent the fair value assigned to technologies that we acquire, which at the time of acquisition have not reached technological feasibility and have no alternative future use. IPR&D is capitalized at its fair value as an indefinite-lived intangible asset, and any development costs incurred after the acquisition are expensed as incurred. During the period that the assets are considered indefinite-lived, they are tested for impairment on an annual basis, or more frequently if we become aware of any events occurring or changes in circumstances that indicate that the fair value of the IPR&D assets are less than their carrying amounts. If and when development is complete, which generally occurs upon regulatory approval and the ability to commercialize products associated with the IPR&D assets, these assets are then deemed definite-lived and are amortized based on their estimated useful lives at that point in time. If development is terminated or abandoned, we may have a full or partial impairment charge related to the IPR&D assets, calculated as the excess of carrying value of the IPR&D assets over fair value.

We conduct an impairment test of IPR&D on an annual basis as of October 1 of each year and will also conduct tests if events occur or circumstances change that would, more likely than not, reduce our fair value below our net equity value.

Contingent Consideration

Consideration paid in a business combination may include potential future payments that are contingent upon the acquired business achieving certain milestones in the future ("contingent consideration"). Contingent consideration liabilities are measured at their estimated fair value as of the date of acquisition, with subsequent changes in fair value recorded in the consolidated statements of operations. We estimate the fair value of the contingent consideration as of the acquisition date using the estimated future cash outflows based on the probability of meeting future milestones. The milestone payments will be made upon the achievement of clinical and commercialization milestones. Subsequent to the date of acquisition, we reassess the actual consideration earned and the probability-weighted future earn-out payments at each balance sheet date. Any adjustment to the contingent consideration liability will be recorded in the consolidated statements of operations. Contingent consideration liabilities expected to be settled within 12 months after the balance sheet date are presented in current liabilities, with the non-current portion recorded under long term liabilities in the consolidated balance sheets.

Results of Operations

Years Ended December 31, 2025 and 2024

General and Administrative Expenses

General and administrative expenses increased to $15.4 million for the year ended December 31, 2025, from $7.4 million for the year ended December 31, 2024. This increase of 109% is primarily comprised of the contingent consideration adjustment of $9.0 million due to the VIRAGE Phase 2b clinical trial of VCN-01 (zabilugene almadenorepvec) in PDAC achieving its primary survival and safety endpoints, offset by a decrease in compensation costs, investor relations costs, consulting fees, and lower director and officer insurance. The charge relating to stock-based compensation expense was $379,000 for the year ended December 31, 2025, compared to $438,000 for the year ended December 31, 2024.

Research and Development Expenses

Research and development expenses decreased to $8.6 million for the year ended December 31, 2025, from $12.0 million for the year ended December 31, 2024. This decrease of 28% is primarily the result of lower clinical trial expenses related to the completion of our VIRAGE Phase 2b clinical trial of VCN-01 (zabilugene almadenorepvec) in PDAC, lower clinical trial expenses related to our Phase 1b/2a clinical trial of SYN-004 (ribaxamase) in allogeneic HCT recipients and lower indirect cost related to compensation, offset by higher patent expenses related to SYN-020. We anticipate research and development expense to decrease in 2026 as a result of the workforce reduction Plan that was implemented on September 30, 2025, the completion of our VIRAGE Phase 2b clinical trial of VCN-01 and our focus on regulatory interactions around potential pivotal clinical trials of VCN-01 in PDAC and retinoblastoma, the planning for VCN-01 manufacturing scale-up activities, and continuing to support our other preclinical and discovery initiatives. In addition, pursuant to the terms of the Rasayana License Agreement that we entered into in February 2026, we will not continue to conduct research and development activities with respect to SYN-020, and do not expect to incur material expenditures in connection therewith since Rasayana is now responsible for all such expenditures including patent expenses. Research and development expenses also include a charge relating to non-cash stock-based compensation expense of $281,000 for the year ended December 31, 2025, compared to $233,000 for the year ended December 31, 2024.

The following table sets forth our research and development expenses directly related to our therapeutic areas for the years ended December 31, 2025 and 2024. These direct expenses were external costs associated with preclinical studies and clinical trials. Indirect research and development costs related to employee costs, facilities, manufacturing, stock-based compensation and research and development support services are not directly allocated to specific drug candidates.

Therapeutic Areas	December 31, 2025 (in thousands)	December 31, 2024 (in thousands)
VCN-01 (zabilugene almadenorepvec)	$ 4,312	$ 6,578
SYN-004 (ribaxamase)	287	790
SYN-020	269	158
Other therapeutic areas	471	404
Total direct costs	5,339	7,930
Total indirect costs	3,265	4,101
Total research and development	$ 8,604	$ 12,031

IPR&D and Goodwill Impairment

During the year ended December 31, 2024, we experienced a sustained decline in the quoted market price of our common stock and we deemed this to be a triggering event for impairment. We performed an interim impairment analysis using the “Income approach” that requires significant judgments, including primarily the estimation of future development costs, the probability of success in various phases of its development programs, potential post - launch cash flows and a risk - adjusted weighted average cost of capital. We concluded that the in-process R&D with a carrying value of $19.8 million was written down to its estimated fair value of $18.6 million and an impairment charge of $1.3 million was recorded, and goodwill with a carrying value of $5.6 million was written down to its estimated fair value of zero and an impairment charge of $5.6 million was recorded during the year ended December 31, 2024. The decrease in the valuation was primarily driven by an increase in the discount rate which was impacted by an increase in the company specific risk premium, and not by material changes to the clinical and administrative operations of the business. There were no impairments during the year ended December 31, 2025.

Total Other Income

Other income was $312,000 for the year ended December 31, 2025, compared to other income of $693,000 for the year ended December 31, 2024. Other income for the year ended December 31, 2025 is primarily comprised of interest income of $287,000 and foreign currency exchange gain of $25,000. Other income for the year ended December 31, 2024 is primarily comprised of interest income of $697,000 and foreign currency exchange loss of $4,000.

Net Loss

Our net loss for the year ended December 31, 2025 was $23.7 million, or ($1.96) per common share, compared to $25.7 million, or ($19.03) per common share for the year ended December 31, 2024.

Liquidity and Capital Resources

As of December 31, 2025, we had a significant accumulated deficit, and with the exception of the three months ended June 30, 2010 and the three months ended December 31, 2017, we have experienced significant losses and incurred negative cash flows since inception. We have incurred an accumulated deficit of $358.7 million as of December 31, 2025, and expect to continue to incur losses in the foreseeable future with the recognition of revenue being contingent on successful Phase 3 clinical trials and requisite approvals by the FDA or foreign equivalents.

Our cash and cash equivalents totaled $13.1 million as of December 31, 2025, an increase of $1.4 million from December 31, 2024. During the years ended December 31, 2025 and 2024, the primary use of cash was for working capital requirements and operating activities which resulted in a net loss of $23.7 million and $25.7 million, respectively.

We believe our cash position of approximately $15.1 million as of early March 2026, will allow us to fund our operations into the first quarter of 2027; however, the current cash will only be sufficient to run certain clinical trials and no assurances can be provided and our cash could differ materially from our expectations based on various factors, many of which are out of our control. Despite this liquidity position, we continue to experience operating losses and face significant uncertainties related to our business model, market conditions, clinical trial outcomes, FDA review timelines and strategic initiatives. These factors raise substantial doubt about our ability to continue as a going concern beyond the next twelve months without additional capital or other strategic actions. Management has developed plans intended to mitigate these uncertainties, including pursuing strategic collaborations, securing additional financing, and prioritizing key development programs. While management believes these plans are probable of being successfully implemented, there can be no assurance that such actions will be sufficient to alleviate the going concern uncertainty.

Based on our current plans, we expect that our cash and cash equivalents will be sufficient to cover overhead costs, close out of the VIRAGE Phase 2b clinical trial, commence and complete a potential Phase 2a study evaluating VCN-01 dosing frequency, exploratory VCN-01 (zabilugene almadenorepvec) manufacturing scale-up activities, regulatory interactions regarding proposed VCN-01 clinical trials in PDAC and retinoblastoma, and preclinical studies supporting VCN-01 and VCN-12, the first candidate from our VCN-X discovery program. We believe that the cash will also be sufficient to fund our committed obligations under the terms of the Purchase Agreement related to the Acquisition, but will not be sufficient for additional trials of VCN-01 or SYN-004 (ribaxamase), or to complete the last cohort of the Phase 1b/2a clinical trial of SYN-004, which are expected to require significant cash expenditures. Following the completion of our ongoing Phase 1 and Phase 2b clinical trials for VCN-01, and preclinical studies supporting VCN-01 and our discovery initiatives, we will need to obtain additional funds for future clinical trials. We anticipate that our future clinical trials will be much larger in size and require larger cash expenditures than the aforementioned clinical programs. We do not have any committed sources of financing for future clinical trials at this time, and it is uncertain whether additional funding will be available when we need it on terms that will be acceptable to us, or at all. Management believes its plan, which is focused on the advancement of VCN-01, will allow us to meet our financial obligations, further advance key products, and maintain our planned operations. Based upon our current available funding and our focus on our clinical development of VCN-01 we do not anticipate that we will fund the last cohort of the Phase 1b/2a clinical trial of SYN-004 and enrollment in this cohort will not commence unless we obtain grant funding, or find a licensee or partner for the SYN-004 development program. However, the amount of additional capital needed by us will also depend upon the costs to advance our VCN-01 clinical programs. We may attempt to utilize the ATM Sales Agreement or seek to raise additional capital in other financing transactions, neither of which is guaranteed. Use of the ATM Sales Agreement is limited by certain restrictions and management's plan does not rely on additional capital from any sources. If we are not able to obtain additional capital (which is not assured at this time), our long-term business plan may not be accomplished, and we may be forced to cease certain development activities. More specifically, the completion of any later stage clinical trial will require significant financing or a significant partnership.

Historically, we have financed our operations primarily through public and private sales of our securities, and we expect to continue to seek and obtain additional capital in a similar manner. During the year ended December 31, 2024, our only source of cash was from sales of our Common Stock through the ATM Sales Agreement pursuant to which we sold 569,000 shares of our Common Stock for net proceeds of $3.6 million and from the sale of our securities in our public offering of 918,600 shares of Common Stock in combination with accompanying warrants to purchase an aggregate of 1,428,600 shares of the Common Stock for gross proceeds of $2.5 million (net proceeds of $2.0 million, after deducting underwriting discounts and estimated expenses). During the three months and year ended December 31, 2025, we sold approximately 17,291,307 and 17,998,117 shares of our Common Stock, respectively, pursuant to the ATM Sales Agreement and received net proceeds of approximately $6.5 million and $6.8 million, respectively. During the first quarter 2026, we sold approximately 10,204,319 shares of our Common Stock pursuant to the ATM Sales Agreement and received net proceeds of approximately $2.3 million. During the year ended December 31, 2025, our primary sources of cash were the approximately $6.8 million in net proceeds received from sales of our Common Stock under the ATM Sales Agreement, approximately $3.9 million in net proceeds from the exercise of the Existing Warrants by holders pursuant to the Inducement Agreement, the $1.7 million received for the Research and Development rebate program offset by the $1.4 million grant receivable recorded in November 2025, $1.4 million for the THERICEL project loan from the National Knowledge Transfer Program of the Spanish government's Ministry of Science and, in May 2025, we closed our May 2025 Offering of 6,818,180 shares of Common Stock (or Pre-Funded Warrants in lieu thereof) in combination with accompanying common stock purchase warrants to purchase an aggregate of 6,818,180 shares of our Common Stock for gross proceeds of $7.5 million (net proceeds of $6.7 million, after deducting underwriting discounts and expenses).

Pursuant to the terms of the Purchase Agreement entered into in connection with the Acquisition, we were required to pay up to $70.2 million in additional consideration upon the achievement of certain milestones, including regulatory filings of which to date $7.3 million has been paid and an additional $5.0 million has been earned but deferred. In September 2022, we received approval from the FDA to proceed with the Phase 2 clinical trial of VCN-01 in metastatic pancreatic ductal adenocarcinoma (mPDAC). Due to this approval, we paid Grifols $3.0 million in the fourth quarter 2022. In August 2023, we initiated patient dosing in the U.S. in our Phase 2 clinical trial of VCN-01 in mPDAC. As a result, payment was made subsequent to September 30, 2023 in the amount of $3.25 million. During the three months ended June 30, 2025, we met the primary survival and safety endpoints in our VIRAGE Phase 2b clinical trial evaluating our lead product candidate VCN-01. As a result of achieving the primary survival and safety endpoints in the Phase 2b clinical trial, we were obligated to pay Grifols $6.0 million. On August 5, 2025, we and Grifols agreed to defer the $6.0 million milestone payment into three payments, as follows: $500,000 was paid in August 2025, $500,000 was paid in December 2025, and the remaining $5.0 million payment has been deferred, pending ongoing discussion with Grifols.

There can be no assurance that we will be able to continue to raise funds through the sale of shares of common stock through the ATM Sales Agreement or other equity financings. If we raise funds by selling additional shares of common stock or other securities convertible into common stock, the ownership interest of our existing stockholders will be diluted. If we are not able to obtain funding for future clinical trials when needed, we will be unable to carry out our business plan and we will be forced to delay the initiation of future clinical trials until such time as we obtain adequate financing and may need to abandon some of our development programs, cease operations, sell or otherwise liquidate our assets or reorganize the Company, or complete a combination of the foregoing.

We have spent, and expect to continue to spend, a substantial amount of funds in connection with implementing our business strategy, including our planned product development efforts, preparation for our planned clinical trials, performance of clinical trials and our research and discovery efforts. We will be required to obtain additional funding in order to continue the development of certain product candidates within the anticipated time periods (including initiation of planned clinical trials), if at all, and to continue to fund operations at the current cash expenditure levels. We anticipate that our current cash of approximately $15.1 million as of early March 2026 will allow us to fund our operations into the first quarter of 2027, including overhead costs, close out of the VIRAGE Phase 2b clinical trial, exploratory VCN-01 manufacturing scale-up activities, regulatory interactions regarding proposed VCN-01 clinical trials in PDAC and retinoblastoma, and preclinical studies supporting VCN-01 and VCN-12, the first candidate from our VCN-X discovery program. We believe the cash will also be sufficient to fund our committed obligations under the terms of the Purchase Agreement related to the Acquisition; however, payment of the $5.0 million owed to Grifols will significantly deplete our cash and cash equivalents, which could materially and adversely affect our liquidity and limit our ability to fund operations or meet other financial obligations. Our ability to continue as a going concern is dependent upon our ability to obtain additional equity or debt financing, attain further operating efficiencies, reduce expenditures, and, ultimately, to generate revenue. Our notes to the consolidated financial statements included in this Annual Report contain an explanatory paragraph referring to our recurring and continuing losses from operations and expressing substantial doubt in our ability to continue as a going concern without additional capital becoming available. We cannot provide any assurance that we will be able to obtain the required funding to achieve our current business plan, obtain the required regulatory approvals for our product candidates or complete additional corporate partnering or acquisition transactions in order to commercialize such product candidates once regulatory approval is received. If we fail to obtain additional funding for our clinical trials, whether through the sale of securities or a partner or collaborator, and otherwise when needed, we will not be able to execute our business plan as planned and will be forced to cease certain development activities (including initiation of planned clinical trials) until funding is received and our business will suffer, which would have a material adverse effect on our financial position, results of operations and cash flows.

Our ability to continue as a going concern is dependent upon our ability to raise additional capital. Our cash and cash equivalents will not be sufficient to initiate or complete future registrational studies for VCN-01, any potential future trials of SYN-004 (ribaxamase) including Phase 3 clinical programs of SYN-004 (ribaxamase) for prevention of CDI or the Phase 1b/2a clinical study of SYN-004 (ribaxamase) in allogeneic HCT recipients. Therefore, we do not intend to commence future new studies of VCN-01 (zabilugene almadenorepvec) or SYN-004 (ribaxamase) until we are confident that we have funding necessary to complete such trials. We are actively pursuing additional equity or debt financing opportunities, in the form of either a private placement or a public offering and have been in ongoing discussions with strategic institutional investors and investment banks with respect to such possible offerings. However, we do not currently have commitments from any third parties to provide us with capital. Potential sources of financing that we are pursuing include strategic relationships, licensing arrangements, public or private sales of our equity (including through the ATM Sales Agreement) or debt and other sources. Such additional financing opportunities might not be available to us when and if needed, on acceptable terms or at all. We cannot assure that we will meet the requirements for use of the ATM Sales Agreement especially in light of the fact that we are currently limited by rules of the SEC as to the number of shares of common stock that we can sell pursuant to the ATM Sales Agreement due to the market value of our common stock held by non-affiliates. Even if we meet the requirements for use of the ATM Sales Agreement, there can be no assurance that we will be able to raise funds through the sale of shares of common stock through the ATM Sales Agreement. Additionally, we may seek to access the public or private equity markets when conditions are favorable due to our long-term capital requirements. If we are unable to obtain additional capital (which is not assured at this time), our long-term business plan may not be accomplished and we may be forced to cease certain development activities. More specifically, the completion of future Phase 3 and/or registrational clinical studies will require significant financing or a significant partnership. If we raise funds by selling additional shares of common stock or other securities convertible into common stock, the ownership interest of our existing stockholders will be diluted. If we are not able to obtain funding for future clinical trials when needed, we will be unable to carry out our business plan and we will be forced to delay the initiation of future clinical trials until such time as we obtain adequate financing and our operating results and prospects will be adversely affected.

Cash Flows

The following table summarizes our cash flows for the periods presented (in thousands):

	Year Ended December 31,	
	2025	2024
Cash used in operating activities	$ (16,669)	$ (16,937)
Cash used in investing activities	(35)	(1)
Cash provided by financing activities	18,193	5,496
Effects of exchange rate changes on cash and cash equivalents	(92)	(132)
Net increase(decrease) in cash	1,397	(11,574)
Cash and cash equivalents, beginning of period	11,705	23,279
Cash and cash equivalents, end of period	$ 13,102	$ 11,705

Cash Used in Operating Activities

Net cash used in operating activities was $16.7 million and $16.9 million during the years ended December 31, 2025 and 2024, respectively, which was primarily due to the use of funds in our operations related to the development of VCN-01 (zabilugene almadenorepvec) our lead product candidate. Cash used in operating activities for the years ended December 31, 2025 decreased compared to the same period in 2024 due primarily to lower research and development expenses and a decrease in interest income, which led to a decrease in net loss.

Cash Used in Investing Activities

Cash used in investing activities during the years ended December 31, 2025 and 2024 was $35,000 and $1,000, respectively, for equipment purchases.

Cash Provided by Financing Activities

Cash provided by financing activities was $18.2 million during the year ended December 31, 2025 compared to $5.5 million during the year ended December 31, 2024. Cash provided by financing activities during the year ended December 31, 2025 included at the market offering proceeds of $6.8 million from sales of 17,998,117 shares of our Common Stock under the ATM Sales Agreement, $1.7 million received for the Research and Development rebate program offset by the $1.6 million grant receivable recorded in November 2025, $1.5 million for the THERICEL project loan from the National Knowledge Transfer Program of the Spanish government's Ministry of Science and, in May 2025, we closed our May 2025 Offering of 6,818,180 shares of Common Stock (or Pre-Funded Warrants in lieu thereof) in combination with accompanying Common Warrants to purchase an aggregate of 6,818,180 shares of the Common Stock for gross proceeds of $7.5 million (net proceeds of $6.7 million, after deducting underwriting discounts and estimated expenses) and net proceeds from warrant inducement of $3.9 million offset by payments related to loans extended by certain Spanish institutions of $70,000 and payment of contingent consideration to Grifols of $1.0 million pursuant to the Purchase Agreement.

License and Contractual Agreement Obligations

We have entered into several license and collaborative agreements for the right to use research, technology and patents. Some of these license and collaborative agreements may contain milestones. The specific timing of such milestones cannot be predicted and are dependent on future developments as well as regulatory actions which cannot be predicted with certainty (including actions which may never occur). Further, under the terms of certain licensing agreements, we may have the obligation to pay certain milestones contingent upon the achievement of specific levels of sales.

Off-Balance Sheet Arrangements

During the years ended December 31, 2025 and 2024, we did not have, and we do not currently have, any off-balance sheet arrangements, as defined under SEC rules.

Consulting Fees

In November 2017, we engaged a regulatory consultant to assist in our efforts to prepare, file and obtain FDA approval for ribaxamase. The term of the engagement was on a monthly basis, provided that either party may terminate the agreement at any time by providing the other party a six-month notice period. We were obligated to pay the consultant a monthly retainer in addition to the success fee payments of up to an aggregate of $4,500,000 for attainment of certain regulatory milestones. We do not deem the contingent fee is probable at this time.

Item 7A. ***Quantitative and Qualitative Disclosures About Market Risk.***

The Company is a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and is not required to provide the information required under this item.

Item 8. ***Financial Statements and Supplementary Data.***

Report of Independent Registered Public Accounting Firm

Shareholders and Board of Directors
Theriva Biologics, Inc.
Rockville, Maryland

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Theriva Biologics, Inc. (the "Company") as of December 31, 2025 and 2024, the related consolidated statements of operations and comprehensive income, stockholders' equity, and cash flows for each of the years then ended, and 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 at December 31, 2025 and 2024, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Going Concern Uncertainty

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the consolidated financial statements, the Company has suffered recurring losses from operations and has not generated positive cash flows from operations which raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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 in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit 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 Matter

The critical audit matter communicated below is a matter 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: (1) relate to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which they relate.

Contingent Consideration - Fair value measurement

As discussed in Note 3 to the consolidated financial statements, during 2022 the Company completed the acquisition of VCN Biosciences ("VCN"). The purchase consideration transferred included contingent consideration of up to $70.2 million based on the achievement of certain clinical and commercialization milestones of an acquired product, VCN-01, and was initially recorded at its estimated fair value as of the date of acquisition. Subsequent to the date of acquisition, the Company reassesses the fair value at each balance sheet date and the contingent consideration liability was recorded at an estimated fair value of $10.0 million as of December 31, 2025 utilizing the discounted cash flow method.

We identified the determination of the fair value of the contingent consideration liability as a critical audit matter. Under the discounted cash flow method, the key estimates and assumptions used in the valuation of the contingent consideration liability included management's determination of the estimated future cash outflows based on the probability of meeting future estimates. Changes to these key estimates and assumptions could have a significant impact on the fair value of the contingent consideration liability. Auditing management's valuation methods and these assumptions involve especially challenging and subjective auditor judgment due to the nature and extent of auditor effort required to address these matters, including the specialized knowledge and skill needed.

The primary procedures we performed to address this critical audit matter included:

- Assessing the reasonableness of management's probability weighted estimates of future earn-out payments based on successful achievement of certain clinical and commercialization milestones by comparing to relevant industry studies.

- Utilizing personnel with specialized knowledge and skills in valuation to assist in: (i) evaluating the appropriateness of the valuation method; and (ii) evaluating the discount rate applied to future milestone payment periods.

/s/ BDO USA, P.C.

We have served as the Company's auditor since 2012.

Raleigh, North Carolina
March 12, 2026

Theriva Biologics, Inc. and Subsidiaries

Consolidated Balance Sheets
(In thousands except share and par value amounts)

	December 31, 2025	December 31, 2024
Assets		
Current Assets		
Cash and cash equivalents	$ 13,056	$ 11,609
Tax credit receivable	3,351	3,228
Prepaid expenses and other current assets	1,060	1,444
Total Current Assets	17,467	16,281
Non-Current Assets		
Property and equipment, net	222	270
Restricted cash	46	96
Right of use asset	803	1,272
In-process research and development	19,619	17,358
Deposits and other assets	82	75
Total Assets	**$ 38,239**	**$ 35,352**
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 1,014	$ 859
Accrued expenses	6,276	3,368
Accrued employee benefits	443	1,144
Deferred research and development tax credit-current portion	1,675	1,614
Loans payable-current	57	61
Operating lease liability-current portion	549	539
Total Current Liabilities	10,014	7,585
Non-current Liabilities		
Non-current contingent consideration	10,004	6,973
Loan Payable - non-current	1,671	92
Non-current deferred research and development tax credit	815	762
Non-current operating lease liability	352	873
Total Liabilities	22,856	16,285
Commitments and Contingencies (Note 12)	—	—
Stockholders' Equity:		
Common stock, $0.001 par value; 350,000,000 shares authorized, 35,717,159 issued and 35,688,350 outstanding at December 31, 2025 and 2,811,259 issued and 2,782,449 outstanding at December 31, 2024	34	3
Additional paid-in capital	373,592	355,501
Treasury stock at cost, 28,809 shares at December 31, 2025 and at December 31, 2024	(288)	(288)
Accumulated other comprehensive income (loss)	755	(1,178)
Accumulated deficit	(358,710)	(334,971)
Total Stockholders' Equity	15,383	19,067
Total Liabilities and Stockholders' Equity	**$ 38,239**	**$ 35,352**

See accompanying notes to consolidated financial statements

Theriva Biologics, Inc. and Subsidiaries

Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share amounts)

	For the year ended December 31,	
	2025	**2024**
Operating Costs and Expenses:		
General and administrative	$ 15,447	$ 7,396
Research and development	8,604	12,031
In-process research and development impairment	—	1,325
Goodwill impairment	—	5,594
Total Operating Costs and Expenses	24,051	26,346
Loss from Operations	(24,051)	(26,346)
Other Income:		
Foreign currency exchange gain (loss)	25	(4)
Interest income	287	697
Total Other Income	312	693
Net Loss before income taxes	(23,739)	(25,653)
Income tax benefit	—	—
Net loss	**$ (23,739)**	**$ (25,653)**
Less deemed dividend from warrant inducement	(1,510)	—
Net Loss Attributable to Common Stockholders	**$ (25,249)**	**$ (25,653)**
Net Loss Per Share - Basic and Dilutive	**$ (2.08)**	**$ (19.03)**
Weighted average number of shares outstanding during the period - basic and dilutive	**12,140,697**	**1,348,126**
Net Loss	**(23,739)**	**(25,653)**
Gain (loss) on foreign currency translation	1,933	(1,210)
Total comprehensive loss	**$ (21,806)**	**$ (26,863)**

See accompanying notes to consolidated financial statements

Theriva Biologics, Inc. and Subsidiaries

Consolidated Statements of Stockholder's Equity
(In thousands, except share and par value amounts)

	Common Stock $0.001 Par Value		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Treasury Stock	Total Stockholders' Equity
	Shares	Amount					
Balance at December 31, 2023	**715,028**	**$ 1**	**$ 346,536**	**$ (309,318)**	**$ 32**	**(288)**	**$ 36,963**
Stock-based compensation	—	—	671	—	—	—	671
Stock issued under "at-the-market" offering	569,282	1	3,602	—	—	—	3,603
Issuance of Common Stock and Warrants, net of issuance costs	918,600	1	1,959	—	—	—	1,960
Series C Preferred Stock conversion to Common	72,132	—	2,005	—	—	—	2,005
Series D Preferred Stock conversion to Common	26,230	—	728	—	—	—	728
Conversion of Pre-Funded Warrants to Common	509,987	—	—	—	—	—	—
Foreign currency exchange loss	—	—	—	—	(1,210)	—	(1,210)
Net loss	—	—	—	(25,653)	—	—	(25,653)
Balance at December 31, 2024	**2,811,259**	**$ 3**	**$ 355,501**	**$ (334,971)**	**$ (1,178)**	**(288)**	**$ 19,067**

	Common Stock $0.001 Par Value		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Treasury Stock	Total Stockholders' Equity
	Shares	Amount					
Balance at December 31, 2024	**2,811,259**	**$ 3**	**$ 355,501**	**$ (334,971)**	**$ (1,178)**	**(288)**	**$ 19,067**
Stock-based compensation	—	—	654	—	—	—	654
Stock issued under "at-the-market" offering	17,998,117	18	6,815	—	—	—	6,833
Issuance of Common Stock and Warrants, net of issuance costs	1,990,900	2	6,688	—	—	—	6,690
Warrant Inducement, net of issuance costs	8,092,280	8	3,933	—	—	—	3,941
Conversion of Pre-Funded Warrants to Common	4,824,603	3	1	—	—	—	4
Foreign currency exchange loss	—	—	—	—	1,933	—	1,933
Net loss	—	—	—	(23,739)	—	—	(23,739)
Balance at December 31, 2025	**35,717,159**	**$ 34**	**$ 373,592**	**$ (358,710)**	**$ 755**	**(288)**	**$ 15,383**

See accompanying notes to consolidated financial statements

Theriva Biologics, Inc. and Subsidiaries

Consolidated Statements of Cash Flows
(In thousands)

	For the year ended December 31,	
	2025	**2024**
Cash Flows From Operating Activities:		
Net loss	$ (23,739)	$ (25,653)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	654	671
In-process research and development impairment	—	1,325
Goodwill impairment	—	5,594
Change in fair value of contingent consideration	9,031	699
Loss on asset disposal	1	—
Non - cash lease expense	522	452
Depreciation	108	137
Deferred research and development tax credit	(188)	(888)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	456	912
Deposits and other assets	—	1
Accounts payable	69	123
Accrued expenses	(2,277)	522
Accrued employee benefits	(744)	(350)
Operating lease liability	(562)	(482)
Net Cash Used In Operating Activities	(16,669)	(16,937)
Cash Flows From Investing Activities:		
Purchases of property and equipment	(35)	(1)
Net Cash Used In Investing Activities	(35)	(1)
Cash Flows From Financing Activities:		
Payment of loans payable	$ (70)	(67)
Proceeds from issuance under at - the - market offering, net of issuance cost	6,833	3,603
Payment of contingent consideration	(1,000)	—
Proceeds from issuance Common Stock and Warrants offering, net of issuance costs	6,690	1,960
Proceeds from warrant inducement	3,942	—
Proceeds from long term debt	1,507	—
Proceeds from issuance of common stock for warrant exercises	4	—
Tax credit receivable	287	—
Net Cash Provided By Financing Activities	18,193	5,496
Effects of exchange rate changes on cash and cash equivalents	(92)	(132)
Net increase (decrease) in cash and cash equivalents and restricted cash	1,397	(11,574)
Cash and cash equivalents and restricted at the beginning of this period	11,705	23,279
Cash and cash equivalents and restricted cash at the end of this period	**$ 13,102**	**$ 11,705**
Reconciliation of cash, cash equivalents, and restricted cash reported in the consolidated balance sheet		
Cash and cash equivalents	13,056	11,609
Restricted cash included in other long-term assets	46	96
Total cash, cash equivalents, and restricted cash shown in the statement of cash flows	**$ 13,102**	**$ 11,705**
NONCASH FINANCING ACTIVITIES:		
Noncash equity issuance costs and deemed dividend	**$ 5,880**	**—**

See accompanying notes to consolidated financial statements

Theriva Biologics, Inc. and Subsidiaries

Notes to Consolidated Financial Statements

1. Organization and Nature of Operations and Basis of Presentation

Description of Business

Theriva Biologics, Inc. (the "Company" or "Theriva Biologics") is a diversified clinical-stage company developing therapeutics designed to treat cancer and related diseases in areas of high unmet need. As a result of the Company's acquisition of Theriva Biologics, S.L. ("VCN", formerly named VCN Biosciences, S.L.), in March 2022 described in more detail below (the "Acquisition"), we transitioned our strategic focus to oncology through the development of VCN's new oncolytic adenovirus platform designed for intravenous and intravitreal delivery to trigger tumor cell death, to improve access of co-administered cancer therapies to the tumor, and to promote a robust and sustained anti-tumor response by the patient's immune system. Our lead product candidate, VCN-01 (zabilugene almadenorepvec), is a clinical stage oncolytic human adenovirus that is modified for tumor-selective replication and to express an enzyme, PH20 hyaluronidase. VCN-01 has been evaluated in a Phase 2b clinical study for the treatment of pancreatic cancer ("VIRAGE"), and a Phase 1 clinical study for the treatment of retinoblastoma, as well as various other Phase 1 clinical studies for the treatment of other solid tumors including head and neck squamous cell carcinoma.

Corporate Structure and Basis of Presentation

On August 15, 2024, the Board of Directors of the Company approved a reverse stock split of the Company's authorized, issued and outstanding shares of common stock, par value $0.001 per share ("Common Stock"), at a ratio of one (1) share of Common Stock for every twenty - five (25) shares of Common Stock (the "Reverse Stock Split"). The Reverse Stock Split went effective on August 26, 2024 (the "Effective Time).

As a result of the Reverse Stock Split, each twenty - five (25) pre-split shares of Common Stock outstanding automatically combined into one (1) new share of common stock without any action on the part of the holders, and the number of outstanding shares of Common Stock was reduced from 25,131,230 shares to 1,005,249 shares and the number of authorized shares of Common Stock was reduced from 350,000,000 shares to 14,000,000 shares and then increased back to 350,000,000 shares of Common Stock after obtaining approval of the Company's shareholders at the 2024 annual meeting of stockholders. Stockholders who otherwise were entitled to receive fractional shares because they held a number of pre-reverse stock split shares of the Company's Common Stock not evenly divisible by 25, received, in lieu of a fractional share, that number of shares rounded up to the nearest whole share. The Reverse Stock Split did not alter the par value of the Company's Common Stock or modify any voting rights or other terms of the Common Stock. In addition, pursuant to their terms, a proportionate adjustment was made to the per share conversion exercise price and number of shares issuable under all of the Company's outstanding shares of convertible preferred stock and stock options and warrants to purchase shares of Common Stock, and the number of shares authorized and reserved for issuance pursuant to the Company's equity incentive plans was reduced proportionately.

All affected share amounts and exercise/conversion prices in the consolidated financial statements and footnotes below have been adjusted retroactively for the Reverse Stock Split.

As of December 31, 2025, the Company had nine subsidiaries, Theriva Biologics, S.L., Pipex Therapeutics, Inc. ("Pipex Therapeutics"), Effective Pharmaceuticals, Inc. ("EPI"), Solovax, Inc. ("Solovax"), CD4 Biosciences, Inc. ("CD4"), Epitope Pharmaceuticals, Inc. ("Epitope"), Healthmine, Inc. ("Healthmine"), Putney Drug Corp. ("Putney") and Synthetic Biomics, Inc. ("SYN Biomics"). Theriva Biologics, S.L.,Pipex Therapeutics, EPI, Healthmine, Putney and SYN Biomics are wholly owned, and Solovax, CD4, and Epitope are majority-owned.

1. Organization and Nature of Operations and Basis of Presentation – (continued)

For financial reporting purposes, the outstanding Common Stock of the Company is that of Theriva Biologics, Inc. All statements of operations, equity and cash flows for each of the entities are presented as consolidated. All subsidiaries were formed under the laws of the State of Delaware on January 8, 2001, except for EPI, which was incorporated in Delaware on December 12, 2000; Epitope which was incorporated in Delaware in January 2002; Putney which was incorporated in Delaware in November 2006; Healthmine which was incorporated in Delaware in December 2007; SYN Biomics which was incorporated in Nevada in December 2013; and Theriva Biologics, S.L. which was incorporated in Spain in December 2022.

Liquidity

As of December 31, 2025, the Company had a significant accumulated deficit of $358.7 million, and the Company has experienced significant losses and incurred negative cash flows since inception. The Company expects to continue incurring losses for the foreseeable future, with the recognition of revenue being contingent on successful Phase 3 clinical trials and requisite approvals by the FDA or foreign equivalents. Historically, the Company has financed its operations primarily through public and private sales of its Common Stock and a private placement of its preferred stock as well as warrant exercises, and it expects to continue to seek to obtain required capital in a similar manner. The Company has spent, and expects to continue to spend, a substantial amount of funds in connection with implementing its business strategy, including planned product development efforts, clinical trials and research and discovery efforts.

The Company's cash and cash equivalents totaled $13.1 million as of December 31, 2025, an increase of $1.4 million from December 31, 2024. During the year ended December 31, 2025, the primary use of cash was for working capital requirements and operating activities which resulted in a net loss of $23.7 million. The Company believes it will be able to fund its operations into the first quarter of 2027. However, the actual amount of additional capital needed by the Company will also depend upon the costs to advance its VCN-01 (zabilugene almadenorepvec) clinical programs. At this time, the Company does not intend to continue to develop SYN-004 and/or SYN-020 internally due to the cost to do so and is seeking out-licenses or partners for such development. The Company may attempt to utilize the at-the-market offering facility ("ATM") or seek to raise additional capital in other financing transactions, neither of which is guaranteed. Use of the ATM is limited by certain restrictions and management's plan does not rely on additional capital from either of these sources. If the Company is not able to obtain additional capital (which is not assured at this time), its business plan may not be accomplished, and it may be forced to cease certain development activities. More specifically, the completion of any later stage clinical trial will require significant financing or a significant partnership.

2. Going Concern

The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern. The Company continues to incur losses and, as of December 31, 2025, the Company had an accumulated deficit of approximately $358.7 million. Since inception, the Company has financed its activities principally from the proceeds of the issuance of equity securities.

The Company's ability to continue as a going concern is dependent upon the Company's ability to raise additional debt and equity capital or secure a potential license or strategic relationship that can help fund its clinical development activities. There can be no assurance that such capital will be available in sufficient amounts or on terms acceptable to the Company. These factors raise substantial doubt about the Company's ability to continue as a going concern. The accompanying consolidated financial statements do not include any adjustments relating to the recoverability of the recorded assets or the classification of liabilities that may be necessary should the Company be unable to continue as a going concern.

2. Going Concern – (continued)

The Company continues to experience operating losses and faces significant uncertainties related to its business model, market conditions, and strategic initiatives. These factors raise substantial doubt about the Company's ability to continue as a going concern beyond the next twelve months without additional capital, or other strategic actions. In order to address the Company's capital needs, including its planned clinical trials, the Company is actively pursuing additional equity or debt financing in the form of either a private placement or a public offering as well as partnerships and other collaborations. The Company has been in ongoing discussions with strategic institutional investors and investment banks with respect to such possible offerings and licensing and/or partnership arrangements. Such additional financing opportunities might not be available to the Company when and if needed, on acceptable terms or at all. If the Company is unable to obtain additional financing in sufficient amounts or on acceptable terms under such circumstances, the Company's operating results and prospects will be adversely affected.

On September 28, 2025, the Board of Directors of the Company approved a plan to resize and restructure the Company (the "Plan") for purposes of focusing its attention on business development and licensing activities and the Company's upcoming meetings with the U.S. Food and Drug Administration and the European Medicines Agency for planned clinical trials in patients with metastatic pancreatic ductal adenocarcinoma ("PDAC") and retinoblastoma. The Company's lead product candidate, VCN-01 (zabilugene almadenorepvec), a clinical stage oncolytic human adenovirus that is modified for tumor-selective replication and to express an enzyme, PH20 or hyaluronidase, has been evaluated in a Phase 2b clinical study for the treatment of pancreatic cancer ("VIRAGE"), and has recently been used to treat patients in a Phase 1 clinical study for the treatment of retinoblastoma.

Pursuant to the Plan, on September 30, 2025, the Company implemented a workforce reduction of seven employees or 32% of the then global Company workforce. The goal of this reduction was to direct the Company's resources towards business development and licensing activities and clinical trial planning and preparation for potential pivotal trials of VCN-01 in patients with PDAC and retinoblastoma, which it believes will represent its best opportunity for success. The Company completed the employee reduction immediately and incurred a total of approximately $520,000 in charges in connection with the workforce reduction. These charges consisted primarily of cash severance and benefits over a three-month period, in connection with the workforce reduction. The Plan is expected to save approximately $1.8 million in compensation and benefits annually beginning in 2026, and together with additional anticipated operating cost reductions the Company expects that it will extend its cash runway into the first quarter of 2027; however, as described below, the current cash will only be sufficient to run certain clinical trials and no assurances can be provided and our cash could differ materially from our expectations based on various factors, many of which are out of our control.

The estimates of the charges and expenditures that the Company expects to incur in connection with the workforce reduction, and the timing thereof, are subject to a number of assumptions, including local law requirements in various jurisdictions, and actual amounts may differ materially from estimates. The Company may also incur other charges or cash expenditures not currently contemplated due to unanticipated events that may occur.

2. Going Concern – (continued)

At December 31, 2025, the Company had cash and cash equivalents of approximately $13.1 million. Based upon the Company's current business plans, management believes that the Company's current cash on hand will be sufficient to fully execute its plans into the first quarter of 2027. Commencement of planned future clinical trials is subject to the Company's successful pursuit of opportunities that will allow it to establish the clinical infrastructure and financial resources necessary to successfully initiate and complete its plan. The Company anticipates its current cash will allow it to cover overhead costs, close out of the VIRAGE Phase 2b clinical trial, exploratory VCN-01 (zabilugene almadenorepvec) manufacturing scale-up activities, regulatory interactions regarding proposed VCN-01 clinical trials in PDAC and retinoblastoma, and preclinical studies supporting VCN-01 and VCN-12, the first candidate from our VCN-X discovery program. The Company also believes that the cash will be sufficient to fund its committed obligations under the terms of the VCN Share Purchase Agreement entered into in connection with the Acquisition (the "Purchase Agreement"), but will not be sufficient for additional trials of VCN-01, or SYN-004, or to complete the last cohort of the Phase 1b/2a clinical trial of SYN-004, which are expected to require significant cash expenditures. Following the completion of the Company's ongoing Phase 1 and Phase 2b clinical trials for VCN-01, complete and commence a potential Phase 2a study evaluating VCN-01 dosing frequency, and preclinical studies supporting VCN-01 and its discovery initiatives, the Company will need to obtain additional funds for future clinical trials. The Company anticipates that its future clinical trials will be much larger in size and require larger cash expenditures than the aforementioned clinical programs and limited preclinical research efforts. Currently, the Company does not have commitments from any third parties to provide it with capital. Potential sources of financing include strategic relationships, public or private sales of equity (including through its Amended and Restated At The Market Issuance Sales Agreement, dated February 9, 2021, as amended by Amendment No. 1 thereto, dated May 3, 2021, as further amended by Amendment No. 2 thereto, dated May 2, 2024 (the "ATM Sales Agreement")) or debt and other sources. The Company cannot assure that it will meet the requirements for use of the ATM Sales Agreement or that additional funding will be available on favorable terms or at all. If the Company fails to obtain additional funding for its clinical trials, whether through the sale of securities or a partner or collaborator, and otherwise when needed, it will not be able to execute its business plan as planned and will be forced to cease certain development activities (including initiation of planned clinical trials) until funding is received and its business will suffer, which would have a material adverse effect on its financial position, results of operations and cash flows.

The actual amount of funds the Company will need to operate is subject to many factors, some of which are beyond its control. These factors include the following:

- the progress of its research activities;
- the number and scope of its research programs;
- the ability to recruit patients for clinical studies in a timely manner;
- the progress of its preclinical and clinical development activities;
- the progress of the development efforts of parties with whom the Company has entered into research and development agreements and amount of funding received from partners and collaborators;
- its ability to maintain current research and development licensing arrangements and to establish new research and development and licensing arrangements;
- the Company's ability to achieve its milestones under licensing arrangements;
- the costs associated with manufacturing-related services to produce material for use in its clinical trials;
- the costs involved in prosecuting and enforcing patent claims and other intellectual property rights; and
- the costs and timing of regulatory approvals.

2. Going Concern – (continued)

The Company has based its estimates of funding requirements on assumptions that may prove to be wrong. The Company may need to obtain additional funds sooner or in greater amounts than it currently anticipates.

If the Company raises funds by selling additional shares of common stock or other securities convertible into common stock, the ownership interest of the existing stockholders will be diluted. If the Company is not able to obtain financing when needed, it may be unable to carry out its business plan. As a result, the Company may have to significantly limit its operations and its business, financial condition and results of operations would be materially harmed.

3. Summary of Significant Accounting Policies

Principles of Consolidation

All intercompany transactions and accounts have been eliminated in consolidation.

Use of Estimates

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Such estimates and assumptions impact, among others, the following: the estimated useful lives for property and equipment, research and development costs, valuation of Goodwill and IPR&D, contingent consideration, and impairment of long-lived assets.

Making estimates requires management to exercise significant judgment. It is at least reasonably possible that the estimate of the effect of a condition, situation or set of consolidated financial statements, which management considered in formulating its estimate could change in the near term due to one or more future confirming events. Accordingly, actual results could differ from those estimates.

Risks and Uncertainties

The Company's operations could be subject to significant risks and uncertainties including financial, operational and regulatory risks and the potential risk of business failure. These conditions may not only limit the Company's access to capital, but also make it difficult for its customers, its vendors and its ability to accurately forecast and plan future business activities.

Cash and Cash Equivalents

Cash and cash equivalents include cash and highly liquid short-term investments with original maturities of three months or less. All interest bearing and non-interest bearing accounts are guaranteed by the Federal Deposit Insurance Corporation ("FDIC") up to $250 thousand. The majority of the Company's cash balances are in excess of FDIC coverage. The Company considers this to be a normal business risk.

3. Summary of Significant Accounting Policies – (continued)

Property and Equipment

Property and equipment is recorded at cost and depreciated or amortized using the straight-line method over the estimated useful life of the asset or the underlying lease term for leasehold improvements, whichever is shorter. The estimated useful life by asset description is noted in the following table.

Asset Description	Estimated Useful Life
Computer, office equipment, furniture and software	3 – 5 years
Leasehold improvements and fixtures	Lesser of estimated useful life or lease term

Depreciation expense was approximately $108,000 and $137,000 for the years ended December 31, 2025 and 2024, respectively. When assets are disposed of, the cost and accumulated depreciation are removed from the accounts with any gain or loss reported in the consolidated statement of operations. Repairs and maintenance are charged to expense as incurred.

The Company reviews property and equipment for impairment to determine if assets are impaired due to obsolescence. As a result of this review, there was no impairment recognized for the years ended December 31, 2025 and 2024.

IPR&D

IPR&D assets represent the fair value assigned to technologies that the Company acquired, which at the time of acquisition have not reached technological feasibility and have no alternative future use. IPR&D assets are considered to have indefinite-lives until the completion or abandonment of the associated research and development projects. If and when development is complete, which generally occurs upon regulatory approval and the ability to commercialize products associated with the IPR&D assets, these assets are then deemed to have definite lives and are amortized based on their estimated useful lives at that point in time. If development is terminated or abandoned, the Company may have a full or partial impairment charge related to the IPR&D assets, calculated as the excess of carrying value of the IPR&D assets over fair value.

During the period that the assets are considered indefinite-lived, they are tested for impairment on an annual basis on October 1, or more frequently if the Company becomes aware of any events occurring or changes in circumstances that could indicate an impairment. The impairment test consists of a comparison of the estimated fair value of the IPR&D with its carrying amount. If the carrying amount exceeds the fair value, an impairment charge is recognized in an amount equal to that excess. The key assumptions used to value IPR&D include estimates of future cash flows and the discount rate applicable to the future cash flow periods.

There were no impairment charges recorded for the year ended December 31, 2025. During the quarters ended June 30, 2024 and September 30, 2024, the Company experienced a sustained decline in the quoted market price of the Company's Common Stock and the Company deemed this to be a triggering event for impairment. The Company performed an interim impairment analysis using both the replacement cost method and the "Income approach" that requires significant judgments, including primarily the estimation of future development costs, the probability of success in various phases of its development programs, potential post - launch cash flows and a risk - adjusted weighted average cost of capital. For the quarter ended June 30, 2024, the Company concluded that the IPR&D was not impaired, however for the quarter ended September 30, 2024, the Company concluded that the in-process R&D with a carrying value of $19.8 million was impaired and was written down to its estimated fair value of $18.6 million and an impairment charge of $1.3 million was recorded. This interim analysis satisfied the requirements of the annual impairment test as the same information would be required for both measurement dates.

3. Summary of Significant Accounting Policies – (continued)

Goodwill Impairment

The Company tests the carrying amounts of goodwill for recoverability on an annual basis on October 1 or more frequently if events or changes in circumstances indicate that the asset might be impaired. The Company performs a one-step test in its evaluation of the carrying value of goodwill if qualitative factors determine it is necessary to complete a goodwill impairment test. In the evaluation, the fair value of the relevant reporting unit is determined and compared to its carrying value. If the fair value is greater than the carrying value, then the carrying value is deemed to be recoverable, and no further action is required. If the fair value estimate is less than the carrying value, goodwill is considered impaired for the amount by which the carrying amount exceeds the reporting unit's fair value, and a charge is reported in impairment of goodwill in the Company's consolidated statements of operations. The key assumptions used to value the reporting unit include estimates of future cash flows, the discount rate applicable and those future cash flow periods. Our estimates of fair value give consideration to the level of implied control premium which is the amount a buyer is willing to pay over the current market price of a company (i.e. market capitalization) to acquire a controlling interest.

During the quarters ended June 30, 2024 and September 30, 2024, the Company experienced a sustained decline in the quoted market price of the Company's Common Stock and the Company deemed this to be a triggering event for impairment. The Company performed an interim impairment analysis using both the "Income approach" that requires significant judgments, including primarily the estimation of future development costs, the probability of success in various phases of its development programs, potential post - launch cash flows and a risk - adjusted weighted average cost of capital. For the quarter ended June 30, 2024, the Company concluded that goodwill with a carrying value of $5.6 million was written down to its estimated fair value of $1.5 million and an impairment charge of $4.1 million was recorded during the quarter ended June 30, 2024. For the quarter ended September 30, 2024 the Company concluded that goodwill with a carrying value of $1.5 million was impaired and was written down to its estimated fair value of zero and an impairment charge of $1.5 million was recorded. This interim analysis satisfied the requirements of the annual impairment test as the same information would be required for both measurement dates.

3. Summary of Significant Accounting Policies – (continued)

Contingent Consideration

Consideration paid in a business combination may include potential future payments that are contingent upon the acquired business achieving certain milestones in the future ("contingent consideration"). Contingent consideration liabilities are measured at their estimated fair value as of the date of acquisition, with subsequent changes in fair value recorded in the consolidated statements of operations. The Company estimates the fair value of the contingent consideration as of the acquisition date using the estimated future cash outflows based on the probability of meeting future milestones. Payments for amounts not in excess of original fair values established at acquisition date (including measurement period adjustments), and not paid within a period considered to be close to the transaction date, are reflected as financing activities in the statement of cash flows. Subsequent to the date of acquisition, the Company reassesses the actual consideration earned and the probability-weighted future earn-out payments at each balance sheet date. The discounted cash flow is the method used to value the contingent consideration which includes inputs of not readily observable market data, which are level 3 inputs. Any adjustment to the contingent consideration liability will be recorded in the consolidated statements of operations. Contingent consideration liabilities expected to be settled within 12 months after the balance sheet date are presented in current liabilities, with the non-current portion recorded under long-term liabilities in the consolidated balance sheets. See Fair Value of Financial Instruments below.

Long-Lived Assets Impairment

Long-lived assets include property, equipment, and right of use assets. Management reviews the Company's long-lived assets for impairment annually or whenever events or changes in circumstances indicate that the carrying amount of an asset or asset group may not be fully recoverable. The judgments made related to the expected useful lives of long-lived assets, definitions of lease terms and the Company's ability to realize undiscounted cash flows in excess of the carrying amounts of these assets are affected by factors such as the ongoing maintenance and improvements of the assets, changes in economic conditions, changes in usage or operating performance and other factors. The Company determines the extent to which an asset may be impaired based upon its expectation of the asset's future usability as well as whether there is reasonable assurance that the future cash flows associated with the asset will be in excess of its carrying amount. If the total of the expected undiscounted future cash flows is less than the carrying amount of the asset, a loss is recognized for the difference between the fair value and the carrying value of the asset. No impairment charges were recorded during the year ended December 31, 2025 and 2024.

Loss per Share

Basic net loss per share is computed by dividing net loss attributable to common shareholders by the weighted average number of common shares outstanding. Diluted net loss per share is computed by dividing net loss by the weighted average number of common shares outstanding including the effect of common share equivalents. Diluted net loss per share assumes the issuance of potential dilutive common shares outstanding for the period and adjusts for any changes in income and the repurchase of common shares that would have occurred from the assumed issuance, unless such effect is anti-dilutive. Net loss attributable to common stockholders for the years ended December 31, 2025 and 2024 was $23.7 million and $25.7 million, respectively. The number of eligible options and warrants for the purchase of Common Stock that were excluded from the computations of net loss per common share for the year ended December 31, 2025 were 1,114,428 and 16,339,060, respectively, and for the year ended December 31, 2024 were 175,034 and 1,428,600, respectively, because their effect is anti-dilutive.

3. Summary of Significant Accounting Policies – (continued)

Research and Development Costs

The Company expenses research and development costs associated with developmental products not yet approved by the FDA to research and development expense as incurred. Research and development costs consist primarily of license fees (including upfront payments), milestone payments, manufacturing costs, salaries, stock-based compensation and related employee costs, fees paid to consultants and outside service providers for laboratory development, legal expenses resulting from intellectual property prosecution and other expenses relating to the design, development, testing and enhancement of the Company's product candidates. Research and development expenses include external contract research organization ("CRO") services. The Company makes payments to the CROs based on agreed upon terms and may include payments in advance of study services. The Company reviews and accrues CRO expenses based on services performed and relies on estimates of those costs applicable to the stage of completion of a study as provided by the CRO. Accrued CRO costs are subject to revisions as such studies progress to completion. At December 31, 2025 and 2024, the Company has accrued CRO expenses of $842,000 and $2.4 million, respectively, that are included in accrued expenses. As of December 31, 2025, and 2024, the Company has prepaid CRO costs of zero and $365,000, respectively, that are included in prepaid expenses.

Leases

The Company assesses all contracts at inception to determine whether a lease exists. The Company's leases are all classified as operating leases per ASC 842. The Company leases office space under operating leases that typically provide for the payment of minimum annual rentals and may include scheduled rent increases. The Company made an accounting policy election to use the practical expedient that allows lessees to treat the lease and non-lease components of leases as a single lease component. Leases with an initial term of 12 months or less are not recorded on the Company's consolidated balance sheets and to recognize those lease payments on a straightline basis in its consolidated statements of operations and comprehensive loss. Operating lease ROU assets and lease liabilities are recognized at commencement date based on the present value of lease payments over the lease term. The Company used the incremental borrowing rate for all of its leases, as the implicit interest rate was not readily determinable. In determining the Company's incremental borrowing rate of each lease, the Company considered recent observable credit spreads correlating to the Company's creditworthiness and the term of each of the Company's lease agreements.

Research and Development Tax Credits

The Company, through its Theriva S.L. subsidiary, participates in a Research and Development incentive program sponsored by the Spanish government. The program provides for reimbursement of certain expenses incurred in research and development efforts the Company incurs in Spain. The program provides for certain limits on the types and amounts of expenses and requires participants to complete a certification and apply for the refund annually. Subsequent to the period in which expenses are incurred, the program requires participants to maintain certain workforce levels and research and development expenditures over a 24-month period. The Company accounts for the reimbursement as a tax credit receivable related to amounts that had been approved by the Spanish government and a corresponding deferred research and development tax credit as it was determined that amounts became probable of being received upon the receipt of the approval. Additionally, the Company has elected to account for the tax credit as a contra-expense as this most appropriately reflects the nature of the transaction and will reduce future research and development expenditures as the Company continues to incur expenses in the upcoming 24-month period.

Stock Warrants

The Company's warrants are exercisable at any time and from time to time, in whole or in part, following the date of issuance and ending five years from the date of the execution of the applicable Warrant Agreement. The warrants were measured at fair value at the date of issuance, which was recorded in additional paid-in capital as a reduction of the gross proceeds raised in the public offering.

3. Summary of Significant Accounting Policies – (continued)

Fair Value of Financial Instruments

Accounting Standards Codification ("ASC") 820, *Fair Value Measurement*, defines fair value as the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is determined based upon assumptions that market participants would use in pricing an asset or liability. Fair value measurements are classified on a three-tier hierarchy as follows:

- Level 1 inputs: Quoted prices (unadjusted) for identical assets or liabilities in active markets;
- Level 2 inputs: Inputs, other than quoted prices, that are observable either directly or indirectly; and
- Level 3 inputs: Unobservable inputs for which there is little or no market data, which require the reporting entity to develop its own assumptions.

In many cases, a valuation technique used to measure fair value includes inputs from multiple levels of the fair value hierarchy described above. The lowest level of significant input determines the placement of the entire fair value measurement in the hierarchy.

The carrying amounts of the Company's short-term financial instruments, including cash and cash equivalents, accounts payable and accrued liabilities, approximate fair value due to the relatively short period to maturity for these level 1 instruments.

As a result of the Acquisition of VCN the Company acquired interest-free or below-market interest rate loans extended by Spanish government. The carrying value of the loans payable approximate fair value and are classified under level 2.

In connection with the Acquisition of VCN, the Company was required to pay up to $70.2 million in additional consideration upon the achievement of certain milestones, including regulatory filings. In September 2022, the Company received approval from the FDA to proceed with the Phase 2 clinical trial of VCN-01 (zabilugene almadenorepvec) in PDAC. Due to this approval the Company paid Grifols Innovation and New Technologies Limited ("Grifols"), $3.0 million in the fourth quarter 2022. In August 2023, the Company initiated patient dosing in the U.S. in its Phase 2 clinical trial of VCN-01 in PDAC. As a result, payment was made subsequent to September 30, 2023 in the amount of $3.25 million. During the year ended December 31, 2025, the Company met the primary survival and safety endpoints in its VIRAGE Phase 2b clinical trial evaluating the Company's lead product candidate VCN-01. As a result of achieving the primary survival and safety endpoints in the Phase 2b clinical trial, the Company is obligated to pay Grifols $6.0 million. On August 5, 2025, the Company and Grifols agreed to defer the $6.0 million milestone payment into three payments, as follows: $500,000 was paid in August 2025, $500,000 was paid in of December 2025, and the remaining $5.0 million payment will be deferred pending ongoing discussions with Grifols. The discounted cash flow method used to value this contingent consideration includes inputs of not readily observable market data, which are Level 3 inputs. The fair value of the contingent consideration was $10.0 million as of December 31, 2025 and is reflected as non-current contingent consideration liability. During the years ended December 31, 2025 and 2024, the Company recognized in operating expense a $9.0 million increase and $699,000 increase, respectfully, fair value adjustment to contingent consideration. There were no transfers in or out of the level 3 liabilities during the years ended December 31, 2025 and 2024, with the exception of the reclassification of $6.0 million related to the milestone that was met during the year ending December 31, 2025 and reclassified to accrued expenses.

3. Summary of Significant Accounting Policies – (continued)

The following table summarizes the change in the fair value as determined by Level 3 inputs for the contingent consideration liabilities for the year ended December 31, 2025 and 2024:

	(in thousands)
Balance at December 31, 2024	$ 6,973
Change in fair value	9,031
Reclassification of amounts to accrued expenses due to milestone being achieved	(6,000)
Balance at December 31, 2025	$ 10,004
Contingent consideration, current portion	$ —
Contingent consideration, net of current portion	10,004
Balance at December 31, 2025	$ 10,004

	(in thousands)
Balance at December 31, 2023	$ 6,274
Change in fair value	699
Balance at December 31, 2024	$ 6,973
Contingent consideration, current portion	$ —
Contingent consideration, net of current portion	6,973
Balance at December 31, 2024	$ 6,973

The fair value of financial instruments measured on a recurring basis is as follows:

	As of December 31, 2025			
Description	**Total**	**Level 1**	**Level 2**	**Level 3**
Liabilities:				
Contingent consideration	$ 10,004	$ —	$ —	$ 10,004
Total liabilities	$ 10,004	$ —	$ —	$ 10,004

	As of December 31, 2024			
Description	**Total**	**Level 1**	**Level 2**	**Level 3**
Liabilities:				
Contingent consideration	$ 6,973	$ —	$ —	$ 6,973
Total liabilities	$ 6,973	$ —	$ —	$ 6,973

3. Summary of Significant Accounting Policies – (continued)

The recurring Level 3 fair value measurements of contingent consideration for which a liability is recorded include the following significant unobservable inputs:

	As of December 31, 2025			
	Valuation Methodology	Significant Unobservable Input	Weighted Average (range, if applicable)	
Contingent Consideration	Discounted Cash Flows	Milestone dates	2026-2031	
		Discount rate	12.3% to 12.6	%
		Weighted Average Discount rate	12.6	%
		Probability of Occurrence (periodic for each Milestone)	11.7% to 92.0	%
		Probability of occurrence (cumulative through each Milestone)	5.3% to 48.8	%

	As of December 31, 2024			
	Valuation Methodology	Significant Unobservable Input	Weighted Average (range, if applicable)	
Contingent Consideration	Discounted Cash Flows	Milestone dates	2026-2028	
		Discount rate	11.6% to 11.8	%
		Weighted Average Discount rate	11.7	%
		Probability of Occurrence (periodic for each Milestone)	11.7% to 92.0	%
		Probability of occurrence (cumulative through each Milestone)	5.3% to 48.8	%

The Company measures certain non - financial assets on a non - recurring basis, including goodwill and in - process R&D on an annual basis on October 1, or more frequently if the Company becomes aware of any events occurring or changes in circumstances that could indicate an impairment. As a result of those measurements, during the year ended December 31, 2024 in - process R&D with a carrying value of $19.8 million was written down to its estimated fair value of $18.6 million and an impairment charge of $1.3 million was recorded, and goodwill with a carrying value of $5.6 million was written down to its estimated fair value of zero and an impairment charge of $5.6 million was recorded. There were no impairment changes during the year ended December 31, 2025. This analysis requires significant judgments, including primarily the estimation of future development costs, the probability of success in various phases of its development programs, potential post - launch cash flows and a risk - adjusted weighted average cost of capital.

The fair value of the Company’s reporting unit was determined using an income approach that utilizes a discounted cash flow model. The discounted cash flow models are dependent upon the Company’s estimates of future cash flows and other factors. The Company’s estimates of future cash flows are based on a comprehensive product by product forecast over a period which covers Phase 1 to approval and 15 years of commercialized revenue and involve assumptions concerning (i) future operating performance, including research and development costs through approval of the drug, the future addressable market, future sales, long - term growth rates, operating margins, allocation and timing of cash flows and the probability of achieving the estimated cash flows and (ii) future economic conditions, all which may differ from actual future cash flows.

3. Summary of Significant Accounting Policies – (continued)

Assumptions related to future operating performance are based on management's annual and ongoing budgeting, forecasting and planning processes and represent the Company's best estimate of the future results of its operations as of a point in time. These estimates are subject to many assumptions, such as the economic environments in which it operates, demand for the products and competitor actions. Estimated future cash flows are discounted to present value using a market participant, weighted average cost of capital, which considers the risk inherent in the probability adjusted future cash flows from each product. The financial and credit market volatility directly impacts certain inputs and assumptions used to develop the weighted average cost of capital such as the risk - free interest rate, industry beta, debt interest rate and the Company's market capital structure. These assumptions are based on significant inputs not observable in the market and thus represent Level 3 measurements within the fair value hierarchy. The use of different inputs and assumptions could increase or decrease the Company's estimated discounted future cash flows, the resulting estimated fair values and the amounts of related goodwill impairments, if any.

Stock-Based Payment Arrangements

Generally, all forms of stock-based payments, including stock option grants, warrants, restricted stock grants and stock appreciation rights are measured at their fair value on the awards' grant date typically using the Black-Scholes option pricing model. Forfeitures are recognized in the period they occur. Stock-based compensation awards issued to non-employees for services rendered are recorded at either the fair value of the services rendered or the fair value of the stock-based payment, whichever is more readily determinable. The expense resulting from stock-based payments is recorded in research and development expense or general and administrative expense in the Consolidated Statements of Operations, depending on the nature of the services provided.

Segment information

The Company's chief operating decision maker ("CODM") is the Company's Chief Executive Officer. The CODM is assisted in his responsibilities of making decisions regarding resource allocation and performance assessment by the leadership team, consisting of the Senior Vice President of Corporate and Product Development.

The Company views its operations and manages its business as one operating segment, focused on the discovery and development of oncolytic viruses intended to overcome the protective barrier surrounding solid tumors and selectively kill tumor cells. The segment-level financial statement information is the same as the financial information presented in the statement of operations and comprehensive loss. The Company monitors its cash and cash equivalents as reported on the Company's Balance Sheets to determine funding for its research and development.

As the Company does not currently generate revenue, the CODM assesses Company performance using the consolidated net loss and through the achievement of pre-clinical and clinical research goals. In addition to the Company's Statement of Operations and Comprehensive Loss, the CODM is regularly provided with budgeted and forecasted expense information which is used to determine the Company's liquidity needs and cash allocation. The measure of segment assets is reported on the consolidated balance sheet as total consolidated assets. The Company's principal operations are in the United States and the Company's long-lived assets are located primarily with in the United States and Spain. The Company held $58,000 and $53,000 of assets in the United States on December 31, 2025 and 2024, respectively. The Company held $164,000 and $216,000 of assets in the Spain on December 31, 2025 and 2024, respectively.

Foreign Currencies

The functional currency of the Company's Theriva S.L. subsidiary is the Euro. Theriva S.L.'s Assets and liabilities are translated to U.S. dollars based on exchange rates at the end of each reporting period. Income and expense items are translated at weighted average exchange rates prevailing during the reporting period. Translation adjustments are accumulated in a separate component of stockholders' equity in the accompanying consolidated balance sheets. Transaction gains and losses are classified as other income (expense) net in the accompanying consolidated statements of operations and comprehensive loss.

3. Summary of Significant Accounting Policies – (continued)

Income Taxes

The Company accounts for income taxes under the liability method; under this method, deferred tax assets and liabilities are determined based on differences between financial reporting and tax reporting bases of assets and liabilities and are measured using enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. Realization of deferred tax assets is dependent upon future earnings, the timing and amount of which are uncertain. The portion of any deferred tax asset for which it is more likely than not that a tax benefit will not be realized must then be offset by recording a valuation allowance.

The Company utilizes a two-step approach to recognize and measure uncertain tax positions. The first step is to evaluate the tax position for recognition by determining if the weight of available evidence indicates that it is more likely than not that the position will be sustained upon tax authority examination, including resolution of related appeals or litigation processes, if any. The second step is to measure the tax benefit as the largest amount that is more than 50% likely of being realized upon ultimate settlement.

Recent Accounting Pronouncements and Developments

In December 2025, the FASB issued ASU 2025-10, Accounting for Government Grants Received by Business Entities (ASU 2025-10), ASU 2025-10 establishes guidance on the recognition, measurement, and presentation of government grants received by business entities. The new guidance leverages the principles in the accounting framework for government assistance in IFRS, specifically IAS 20, Accounting for Government Grants and Disclosure of Government Assistance; makes certain targeted improvements; and modifies certain of the existing disclosure requirements in ASC 832, Government Assistance. The new guidance is effective for public business entities in annual periods beginning after December 15, 2028 (including interim periods within) and one year later for all other entities, with early adoption permitted in any period for which financial statements have not yet been issued. The guidance can be applied on a modified prospective basis, a modified retrospective basis, or a full retrospective basis. The Company is currently evaluating the potential impact of the guidance and potential additional disclosures required.

In December 2025, the FASB issued ASU 2025-11, Interim Reporting (Topic 270): Narrow-Scope Improvements (“ASU 2025-11”). ASU 2025-11 is intended to clarify and improve certain aspects of interim financial reporting, including the requirements for interim disclosures and the application of recognition and measurement guidance in interim periods. ASU 2025-11 is effective for interim reporting periods within annual reporting periods beginning after December 15, 2026. The Company is currently evaluating the potential impact of the guidance and potential additional disclosures required.

In November 2025, the FASB issued ASU 2025-09, Derivatives and Hedging (Topic 815): Hedge Accounting Improvements (“ASU 2025-09”). ASU 202509 expands eligibility of risk components for hedge designation, clarifies the presentation and disclosure requirements for hedging relationships, and simplifies the assessment of hedge effectiveness. ASU 2025-09 is effective for annual periods beginning after December 15, 2026, including interim periods within those fiscal years. The Company is currently evaluating the potential impact of the guidance and potential additional disclosures required.

On November 2024, the FASB issued ASU 2024-03 - Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses. The ASU requires more detailed disclosures about the types of expenses in commonly presented expense captions such as cost of sales, selling, general and administrative expenses and research and development expenses. This includes separate footnote disclosure for expenses such as purchases of inventory, employee compensation, depreciation, and intangible asset amortization. Public business entities are required to apply the guidance prospectively and may apply it retrospectively. The ASU’s amendments are effective for public business entities for annual periods beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027. Public business entities are required to apply the guidance prospectively and may apply it retrospectively. The Company is currently evaluating the effect of adopting this ASU.

In December 2023, the FASB issued final guidance in ASU No. 2023-09, Income Taxes (ASC 740): Improvements to Income Tax Disclosures requiring entities to provide additional information in the rate reconciliation and disclosures about income taxes paid. For public business entities, the guidance is effective for annual periods beginning after December 15, 2024. The Company adopted the provisions of ASU 2023-09 for the annual period ending December 31, 2025. See Income Taxes footnote 13.

4. Intangibles

The following table provides the Company's Goodwill as of December 31, 2024.

	Goodwill (in thousands)
Balance at December 31, 2023	$ 5,700
Goodwill impairment	(5,594)
Effects of exchange rates	(106)
Balance at September December 31, 2024	$ —

The following table provides the Company's in-process R&D as of December 31, 2025.

	In-process R&D (in thousands)
Balance at December 31, 2023	$ 19,755
In-process R&D impairment	(1,325)
Effects of exchange rates	(1,072)
Balance at December 31, 2024	$ 17,358
Effects of exchange rates	2,261
Balance at December 31, 2025	$ 19,619

On October 1, 2025, the Company performed its annual impairment test. The impairment test consists of a comparison of the estimated fair value of the IPR&D with its carrying amount. If the carrying amount exceeds the fair value, an impairment charge is recognized in an amount equal to that excess. The key assumptions used to value IPR&D include estimates of future cash flows and the discount rate applicable to the future cash flow periods. There were no impairment charges recorded during the year ended December 31, 2025.

During the quarters ended June 30, 2024 and September 30, 2024, the Company experienced a sustained decline in the quoted market price of the Company's Common Stock and the Company deemed this to be a triggering event for impairment. The Company performed an interim impairment analysis using both the replacement cost method and the "Income approach" that requires significant judgments, including primarily the estimation of future development costs, the probability of success in various phases of its development programs, potential post-launch cash flows and a risk-adjusted weighted average cost of capital.

For the quarter ended June 30, 2024, the Company concluded that goodwill with a carrying value of $5.6 million was written down to its estimated fair value of $1.5 million and an impairment charge $4.1 million was recorded during the quarter ended June 30, 2024. For the quarter ended September 30, 2024 the Company concluded that goodwill with a carrying value of $1.5 million was impaired and was written down to its estimated fair value of zero and an impairment charge of $1.5 million was recorded. This interim analysis satisfied the requirements of the annual impairment test as the same information would be required for both measurement dates.

For the quarter ended June 30, 2024 the Company concluded that the IPR&D was not impaired however, for the quarter ended September 30, 2024, the Company concluded that the in-process R&D with a carrying value of $19.8 million was impaired and was written down to its estimated fair value of $18.6 million and an impairment charge of $1.3 million was recorded. This interim analysis satisfied the requirements of the annual impairment test as the same information would be required for both measurement dates.

5. Research and Development Tax Credits

The Company, through its Theriva S.L. subsidiary, participates in a Research and Development program sponsored by the Spanish government. The program provides for reimbursement of certain expenses incurred in research and development efforts the Company conducts in Spain. The reimbursements can be through either tax credits or direct refunds. The program provides for certain limits on the types and amounts of expenses for which reimbursement may be sought and requires participants to complete a certification and apply for the refund annually. Subsequent to the period in which expenses are incurred, the program requires participants to maintain certain workforce levels and research and development expenditures over a 24-month period.

During the quarter ended June 30, 2025, the Company completed the certification and applied for direct reimbursement for its qualifying research and development expenses incurred in the year ended December 31, 2024. The Company received approvals from the Spanish government in November 2025. During the quarter ended June 30, 2024, the Company completed the certification and applied for direct reimbursement for its qualifying research and development expenses incurred in the year ended December 31, 2023. The Company received approvals from the Spanish government in December 2024.

The Company evaluated the program and concluded that it qualified to be accounted for as government assistance. Accordingly, the Company, as allowed by U.S. GAAP, elected to account for the grant by analogizing to the guidance provided by International Accounting Standards ("IAS") 20, Accounting for Government Grants and Disclosure of Government Assistance. Accordingly, the Company recognized a tax credit receivable of $3.4 million related to amounts that had been approved by the Spanish government and a corresponding deferred research and development tax credit current portion of $1.7 million and a deferred research and development tax credit non-current portion of $815,000 as it was determined that amounts became probable of being received upon the receipt of the approval. Additionally, the Company has elected to account for the tax credit as a contra-expense as this most appropriately reflects the nature of the transaction and will reduce future research and development expenditures as the Company continues to incur expenses in the upcoming 24-month period. During the year ending December 31, 2025 and 2024 the Company recorded $1.8 million and $888,000, respectively, as a reduction in research and development expense.

6. Selected Balance Sheet Information

PREPAID EXPENSES AND OTHER CURRENT ASSETS (in thousands):

	December 31, 2025	December 31, 2024
Stock sales receivable	$ 452	$ —
Prepaid insurance	350	374
Prepaid consulting, subscriptions and other expenses	213	235
VAT receivable	32	95
Prepaid manufacturing expenses	13	375
Prepaid clinical research organizations	—	365
Total prepaid expenses and other current assets	$ 1,060	$ 1,444

Stock sales receivable is from at-the-market stock sales that have not cash settled prior to the period end.

Prepaid CROs expense is classified as a current asset. The Company makes payments to the CROs based on agreed upon terms that include payments in advance of study services.

PROPERTY AND EQUIPMENT (in thousands)

	December 31, 2025	December 31, 2024
Computers and office equipment	$ 639	$ 708
Other property, plant and equipment	444	392
Leasehold improvements	94	94
Software	11	11
	1,188	1,205
Less: accumulated depreciation and amortization	(966)	(935)
Total property and equipment, net	$ 222	$ 270

During the years ended December 31, 2025 and 2024 the Company recognized depreciation expense of $108,000 and $137,000 respectively.

6. Selected Balance Sheet Information – (continued)

ACCRUED EXPENSES (in thousands)

	December 31, 2025	December 31, 2024
Accrued milestones payments	$ 5,000	$ —
Accrued clinical consulting services	842	2,390
Accrued manufacturing costs	257	772
Accrued vendor payments	177	206
Total accrued expenses	$ 6,276	$ 3,368

ACCRUED EMPLOYEE BENEFITS (in thousands)

	December 31, 2025	December 31, 2024
Accrued bonus expense	$ 247	$ 870
Accrued compensation expense	153	187
Accrued vacation expense	43	87
Total accrued employee benefits	$ 443	$ 1,144

7. Stock-Based Compensation

Stock Incentive Plan

On November 2, 2010, the Company's Board of Directors and stockholders adopted the 2010 Stock Incentive Plan ("2010 Stock Plan") for the issuance of up to 343 shares of Common Stock to be granted through incentive stock options, nonqualified stock options, stock appreciation rights, dividend equivalent rights, restricted stock, restricted stock units and other stock-based awards to officers, other employees, directors and consultants of the Company and its subsidiaries. From time to time the number of shares authorized for awards was increased such that 16,000 shares were authorized as of September 5, 2019. The exercise price of stock options under the 2010 Stock Plan was determined by the compensation committee of the Board of Directors and could be equal to or greater than the fair market value of the Company's Common Stock on the date the option was granted. Options become exercisable over various periods from the date of grant and expire between five and ten years after the grant date. As of December 31, 2025, there were 5,893 options issued and outstanding under the 2010 Stock Plan. There are no shares available to be issued under this plan. Only options were issued under the plan.

On September 17, 2020, the Company's stockholders approved and adopted the 2020 Stock Incentive Plan ("2020 Stock Plan") for the issuance of up to 16,000 shares of Common Stock to be granted through incentive stock options, nonqualified stock options, stock appreciation rights, dividend equivalent rights, restricted stock, restricted stock units and other stock-based awards to officers, other employees, directors and consultants of the Company and its subsidiaries. The number of shares authorized for awards under the 2020 Stock Plan was increased such that 4,500,000 shares were authorized as of December 31, 2025. As of December 31, 2025, there were 1,108,535 options issued and outstanding under the 2020 Stock Plan. Only options have been issued under the plan.

7. Stock-Based Compensation – (continued)

In the event of an employee's termination, the Company will cease to recognize compensation expense for that employee. Stock option forfeitures are recognized as incurred. The fair value of the stock-based payment is recognized over the stated vesting period.

The Company has applied fair value accounting for all stock-based payment awards since inception. The fair value of each option granted is estimated on the date of grant using the Black-Scholes option pricing model. The assumptions used for the years ended December 31, 2025 and 2024 are as follows:

	Year ended December 31,	
	2025	2024
Exercise price	$ 1.41	$ 5.25
Expected dividends	— %	— %
Expected volatility	107.4 %	93.38 %
Risk free interest rate	3.74 %	3.88 %
Expected life of option (years)	4.23	4.26

Expected dividends —The Company has never declared or paid dividends on its Common Stock and has no plans to do so in the foreseeable future.

Expected volatility—Volatility is a measure of the amount by which a financial variable such as a share price has fluctuated (historical volatility) or is expected to fluctuate (expected volatility) during a period. The expected volatility assumption is derived from the historical volatility of the Company's Common Stock over a period approximately equal to the expected term.

Risk-free interest rate—The assumed risk-free rate used is a zero coupon U.S. Treasury security with a maturity that approximates the expected term of the option.

Expected life of the option—The period of time that the options granted are expected to remain unexercised. Options granted during the years ended 2025 and 2024 have a maximum term of seven years. The Company estimates the expected life of the option term based on the weighted average life between the dates that options become fully vested and the maximum life of options granted.

7. Stock-Based Compensation – (continued)

The Company records stock-based compensation based upon the stated vesting provisions in the related agreements. The vesting provisions for these agreements have various terms as follows:

- immediate vesting,
- in full on one-year anniversary date of grant date,
- half vesting immediately and remaining over three years,
- quarterly over three years,
- annually over three years,
- one-third immediate vesting and remaining annually over two years,
- one-half immediate vesting and remaining over nine months,
- one-quarter immediate vesting and remaining over three years,
- one-quarter immediate vesting and remaining over 33 months,
- monthly over one year, and
- monthly over three years.

During the years ended December 31, 2025 and 2024, the Company granted 951,500 and 420, respectively, options to purchase shares of Common Stock to employees and directors having an approximate fair value of $1.0 million and $1,500, respectively, based upon the Black-Scholes option pricing model, respectively.

Stock-based compensation expense included in general and administrative expenses and research and development expenses relating to stock options issued to employees for the years ended December 31, 2025 and 2024 was $517,000 and $462,000, respectively. Stock-based compensation expense included in general and administrative expenses and research and development expenses relating to stock options issued to consultants for the years ended December 31, 2025 and 2024 was $137,000 and $209,000, respectively.

7. Stock-Based Compensation – (continued)

A summary of stock option activity for the years ended December 31, 2025 and 2024 is as follows:

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value
Balance - December 31, 2023	175,049	$ 45.55	7.70 years	$ —
Granted	420	5.25		
Expired	(435)	3,499		
Forfeited	—	—		
Balance - December 31, 2024	175,034	36.88	6.72 years	—
Granted	951,500	1.41		
Expired	(1,777)	1,268		
Forfeited	(10,329)	14.72		
Balance - December 31, 2025 - outstanding	1,114,428	$ 4.84	6.12 years	$ —
Balance - December 31, 2025 - exercisable	517,724	$ 8.33	4.18 years	$ —
Grant date fair value of options granted - December 31, 2025		$ 1,011,295		
Weighted average grant date fair value - December 31, 2025		$ 1.06		
Grant date fair value of options granted - year ended December 31, 2024		$ 1,526		
Weighted average grant date fair value - year ended December 31, 2024		$ 3.63		

The options outstanding and exercisable at December 31, 2025 are as follows:

Options Outstanding				Options Exercisable		
Range of Exercise Price	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life
$ 0.00 – $60.00	1,093,993	$ 3.13	6 years	497,289	$ 4.72	4 years
61.00 – $120.00	20,083	94.92	2 years	20,083	94.92	2 years
121.00 – $180.00	352	172.25	1 years	352	172.25	1 years

7. Stock-Based Compensation – (continued)

As of December 31, 2025, total unrecognized stock-based compensation expense related to stock options was $694,000 which is expected to be expensed through January 2028.

The FASB's guidance for stock-based payments requires cash flows from excess tax benefits to be classified as a part of cash flows from operating activities. Excess tax benefits are realized tax benefits from tax deductions for exercised options in excess of the deferred tax asset attributable to stock compensation costs for such options. The Company did not record any excess tax benefits in 2025 or 2024. Cash received from option exercises under the Company's stock-based compensation plans for the years ended December 31, 2025 and 2024 was zero.

8. Stock Warrants

On September 27, 2024, the Company consummated a public offering (the "2024 Offering") of an aggregate of (i) 918,600 shares of Common Stock, (ii) pre-funded warrants (the "2024 Pre-Funded Warrants") to purchase up to 510,000 shares of Common Stock (the "2024 Pre-Funded Warrant Shares"), and (iii) Common Stock purchase warrants (the "2024 Common Warrants") to purchase up to 1,428,600 shares of Common Stock (the "Common Warrant Shares"). Each Share and associated 2024 Common Warrant was sold at a combined public offering price of $1.75. Each 2024 Pre-Funded Warrant and associated 2024 Common Warrant was sold at a combined public offering price of $1.7499. The Company received aggregate gross proceeds from the 2024 Offering of approximately $2.5 million, before deducting placement agent fees and other offering expenses. Each 2024 Pre-Funded Warrant was immediately exercisable for one share of Common Stock at an exercise price of $0.0001 per share and was to remain exercisable until the 2024 Pre-Funded Warrants are exercised in full. Each 2024 Common Warrant has an exercise price of $2.00 per share, is immediately exercisable for one (1) share of Common Stock, and expires five (5) years from its issuance date. The shares of Common Stock, 2024 Pre-Funded Warrants and accompanying 2024 Common Warrants were issued separately. The exercise price of the 2024 Common Warrants and the 2024 Pre-Funded Warrants and number of shares of Common Stock issuable upon exercise will adjust in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events. The 2024 Common Warrants may be exercised on a cashless basis if at the time of exercise thereof there is no effective registration statement registering, or the prospectus contained therein is not available for, the issuance of the Common Stock issuable upon exercise of the 2024 Common Warrants to the holder. The 2024 Pre-Funded Warrants could be exercised on a cashless basis at any time. A holder of the 2024 Common Warrants and the 2024 Pre-Funded Warrants (together with its affiliates) may not exercise any portion of the 2024 Common Warrant or 2024 Pre-Funded Warrant to the extent that the holder would own more than 4.99% (or 9.99%, at the election of the holder) of the outstanding shares of Common Stock immediately after exercise, except that upon at least 61 days' prior notice from the holder to the Company, the holder may increase the amount of beneficial ownership of outstanding shares after exercising the holder's 2024 Common Warrants or 2024 Pre-Funded Warrants up to 9.99% of the number of the Company's shares of Common Stock outstanding immediately after giving effect to the exercise. The Company has concluded that the 2024 Common Warrants and 2024 Pre-Funded Warrants are required to be equity classified. The 2024 Common Warrants were valued on the date of grant using Black Scholes model. During the year ended December 31, 2024, there were zero 2024 Common Warrants exercised and as of December 31, 2024, all 510,000 2024 Pre-Funded warrants were exercised. During the year ended December 31, 2025 there were 1,345,000 2024 Common Warrants exercised in the October 17, 2025 warrant inducement.

8. Stock Warrants – (continued)

On May 8, 2025 the Company consummated a public offering (the "May 2025 Offering") of an aggregate of (i) 1,990,900 shares of Common Stock, (ii) pre-funded warrants (the "2025 Pre-Funded Warrants") to purchase up to 4,827,280 shares of common stock (the "2025 Pre-Funded Warrant Shares"), and (iii) Common Stock purchase warrants (the "2025 Common Warrants") to purchase up to 6,818,180 shares of common stock (the "2025 Common Warrant Shares"). Each share of Common Stock and associated 2025 Common Warrant was sold at a combined public offering price of $1.10. Each 2025 Pre-Funded Warrant and associated 2025 Common Warrant was sold at a combined public offering price of $1.099. The Company received aggregate gross proceeds from the May 2025 Offering of approximately $7.5 million, before deducting placement agent fees and other offering expenses. Each 2025 Pre-Funded Warrant was immediately exercisable for one (1) share of Common Stock at an exercise price of $0.001 per share and will remain exercisable until such 2025 Pre-Funded Warrant is exercised in full. Each 2025 Common Warrant has an exercise price of $1.10 per share of Common Stock, is immediately exercisable, and expires five (5) years from its issuance date. The exercise price of the 2025 Common Warrants and the 2025 Pre-Funded Warrants and number of shares of common stock issuable upon exercise will be adjusted in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events. In the event of a fundamental transaction, as described in each of the 2025 Common Warrants and the 2025 Pre-Funded Warrants, the holders of such warrants will be entitled to receive upon exercise of their respective warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised their warrants immediately prior to such fundamental transaction. In addition, in certain circumstances, upon a fundamental transaction, a holder of 2025 Common Warrants will have the right to require us to repurchase its 2025 Common Warrants at the Black Scholes Value; provided, however, that, if the fundamental transaction is not within the Company's control, including not approved by the Company's board of directors, then the holder shall only be entitled to receive the same type or form of consideration (and in the same proportion), at the Black Scholes Value of the unexercised portion of the 2025 Common Warrant, that is being offered and paid to the holders of common stock in connection with the fundamental transaction. The 2025 Common Warrants may be exercised on a cashless basis if at the time of exercise thereof there is no effective registration statement registering, or the prospectus contained therein is not available for, the issuance of the share of Common Stock issuable upon exercise thereof to the holder. The 2025 Pre-Funded Warrants may be exercised on a cashless basis at any time.

A holder of the 2025 Common Warrants and the 2025 Pre-Funded Warrants (together with its affiliates) may not exercise any portion of the 2025 Common Warrant or 2025 Pre-Funded Warrant to the extent that the holder would own more than 4.99% (or 9.99%, at the election of the holder) of the outstanding shares of Common Stock immediately after exercise, except that upon at least 61 days' prior notice from the holder to the Company, the holder may increase the amount of beneficial ownership of outstanding shares after exercising the holder's 2025 Common Warrants or 2025 Pre-Funded Warrants up to 9.99% of the number of the Company's shares of common stock outstanding immediately after giving effect to the exercise. The Company has concluded that the 2025 Common Warrants and 2025 Pre-Funded Warrants are required to be equity classified. The 2025 Common Warrants were valued on the date of grant using Black Scholes model. During the year ended December 31, 2025, all 4,827,280 2025 Pre-Funded Warrants issued in the May 2025 Offering were exercised. During the year ended December 31, 2025 there were 6,747,280 2025 Common Warrants exercised with the October 17, 2025 warrant inducement.

On October 16, 2025, the Company entered into a warrant inducement agreement (the "Inducement Agreement") with certain holders named therein (the "Holders") of existing Common Stock Purchase Warrants to purchase up to an aggregate of 8,092,280 shares of the Company's common stock, consisting of (i) Common Stock Purchase Warrants to purchase up to an aggregate of 1,345,000 shares of common stock issued on September 27, 2024 (the "September Warrants") and (ii) Common Stock Purchase Warrants to purchase up to an aggregate of 6,747,280 shares of common stock issued on May 8, 2025 (the "May Warrants" and, together with the September Warrants, the "Existing Warrants"). Pursuant to the Inducement Agreement, on October 17, 2025, the Holders exercised for cash the Existing Warrants at a reduced exercise price of $0.54 per share and, in consideration therefor, the Company issued to the Holders new Common Stock Purchase Warrants (the "New Warrants") to purchase an aggregate of 16,184,560 shares of common stock, equal to 200% of the number of shares of Common Stock underlying the Existing Warrants, at an exercise price of $0.54 per share, which New Warrants are exercisable for a term of five (5) years from the date of the approval from the stockholders of the Company of the full exercise of the New Warrants and the issuance of all of the shares of common stock issuable upon the exercise thereof, which had not occurred as of December 31, 2025.

8. Stock Warrants – (continued)

The Company received aggregate gross proceeds of approximately $4.4 million for the exercise of the Existing Warrants, before deducting placement agent fees of $356,000 and other expenses of $72,000 payable by the Company. AGP served as the Company's exclusive financial advisor in connection with the warrant exercise and other transactions described in the Inducement Agreement. Pursuant to the terms of an engagement letter, dated October 16, 2025, by and between the Company and AGP, the Company agreed to pay to AGP a cash fee equal to 7.0% of the aggregate gross proceeds received from the Holder upon exercise of the Existing Warrants and reimbursement of certain expenses. The Company evaluated the facts and circumstances of the inducement transaction and concluded that the issuance of the new warrants, issued to induce the existing warrant holders to exercise their original warrants, was directly attributable to an equity issuance. Accordingly, the Company recognized the increase in value transferred to the holders as an equity issuance cost. The increase in value transferred to holders was measured as the difference between the fair value of the new warrants and the fair value of the original warrants at the modification date, totaling $5.9 million. The increased value provided by the modification and the issuance of new warrants in excess of the gross proceeds of $1.5 million was accounted for as a deemed dividend and increased net loss available to common shareholders for purposes of calculating loss per share. The Company determined the fair value of the new warrants and original warrants on the modification date through the use of a Black Scholes model. The increase in value transferred to the holders was recognized as a decrease to additional paid in capital, which offset the recording of the new warrants, thereby resulting in no net impact to total equity.

A summary of all warrant activity for the Company for the year ended December 31, 2025 and the year ended December 31, 2024 is as follows:

	Number of Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life
Balance at December 31, 2023	—	$ —	—
Granted	1,938,600	1.47	4.74 years
Exercised	(510,000)	0.0001	—
Forfeited	—	—	—
Balance at December 31, 2024	1,428,600	2.0	4.74 years
Granted	27,830,020	0.58	4.73
Exercised	(12,919,560)	0.78	—
Forfeited	—	—	—
Balance at December 31, 2025	16,339,060	0.55	4.99

9. Stockholders' Equity

Series C and D Preferred Stock

On July 29, 2022, the Company closed a private placement offering pursuant to the terms of a Securities Purchase Agreement dated as of July 28, 2022 entered into with MSD Credit Opportunity Master Fund, L.P. (the "Securities Purchase Agreement"), pursuant to which the Company issued and sold 275,000 shares of the Company's Series C Convertible Preferred Stock, par value $0.001 per share (the "Series C Preferred Stock"), and 100,000 shares of the Company's Series D Convertible Preferred Stock, par value $0.001 per share (the "Series D Preferred Stock," and together with the Series C Preferred Stock, the "Preferred Stock"), at an offering price of $8.00 per share, for gross proceeds of approximately $3.0 million in the aggregate, before the deduction of discounts, fees and offering expenses. The shares of Preferred Stock were convertible, at a conversion price (the "Conversion Price") of $1.22 per share (subject in certain circumstances to adjustments), into an aggregate of 2,459,016 shares of the Company's common stock, at the option of the holders of the Preferred Stock and, in certain circumstances, by the Company. The Securities Purchase Agreement contained customary representations, warranties and agreements by the Company and customary conditions to closing.

The Company included certain proposals at its 2022 annual meeting of stockholders, including (i) an amendment to the Company's Articles of Incorporation, as amended (the "Charter"), to change the name of the Company to "Theriva Biologics, Inc." (the "Name Change"), (ii) an amendment to the Charter to increase the number of authorized shares of common stock from 20,000,000 to 350,000,000 (the "Authorized Common Stock Increase") and (iii) to adjourn any meeting of stockholders called for the purpose of voting on the Authorized Common Stock Increase (collectively, the "Stockholder Items"). The purchaser of the Preferred Stock agreed in the Purchase Agreement to (i) not transfer, offer, sell, contract to sell, hypothecate, pledge or otherwise dispose of the shares of the Preferred Stock until the earlier of the date that the Authorized Common Stock Increase being proposed at the 2022 annual meeting of stockholders was effected or October 26, 2022 and (ii) vote the shares of the Series C Preferred Stock purchased in the Offering in favor of the Stockholder Items. The Authorized Common Stock Increase was effected on October 26, 2022.

Pursuant to the Securities Purchase Agreement, the Company filed certificates of designation (the "Certificates of Designation") with the Secretary of the State of Nevada designating the rights, preferences and limitations of the shares of Series C Preferred Stock and Series D Preferred Stock. The Certificate of Designation for the Series C Preferred Stock provides, in particular, that the Series C Preferred Stock will have no voting rights other than the right to vote as a class on the Stockholder Items (as defined therein) and the right to cast votes on an as converted to common stock basis on the Stockholder Items. The Certificate of Designation for the Series D Preferred Stock provides, in particular, that the Series D Preferred Stock will have no voting rights other than the right to vote as a class on the Stockholder Items and the right to cast 20,000 votes per share of Series D Preferred Stock on the Stockholder Items and to vote the shares of the Series D Preferred Stock purchased in the offering in the same proportion as shares of common stock and any other shares of capital stock of the Company that are entitled to vote thereon (excluding any shares of common stock that are not voted) on the Stockholder Items.

The holders of Preferred Stock were entitled to dividends, on an as-if converted basis, equal to dividends actually paid, if any, on shares of common stock. The Conversion Price may be adjusted pursuant to the Certificates of Designation for stock dividends and stock splits, subsequent rights offering, pro rata distributions of dividends or the occurrence of a fundamental transaction (as defined in the applicable Certificate of Designation).

The Series C Preferred Stock and Series D Preferred Stock were classified as temporary equity as a result of the deemed liquidation provision. Transaction expenses paid to third parties were charged to temporary equity and were not to be accreted as deemed dividends until redemption becomes probable.

During year ending December 31, 2024, the Company issued 72,132 shares of its Common Stock upon the conversion effected by the holder of the Series C Preferred Stock of 275,000 shares of its Series C Preferred Stock at a conversion price of $30.50 per share. As a result of the conversions during the year ending December 31, 2024, the Company reduced the Series C Preferred Stock $2.0 million and Additional Paid in Capital $2.0 million. There are no shares of Series C Preferred Stock outstanding as of December 31, 2025.

9. Stockholders' Equity – (continued)

During year ending December 31, 2024, the Company issued 26,230 shares of its Common Stock upon the conversion effected by the holder of the Series D Preferred Stock of 100,000 shares of its Series D Preferred Stock at a conversion price of $30.50 per share. As a result of the conversion during the year ending December 31, 2024 the Company reduced the Series D Preferred Stock to $728,000 and Additional Paid in Capital $728,000. There are no shares of Series D Preferred Stock outstanding as of December 31, 2025.

At Market Issuance Sales Agreement

On May 2, 2024, the Company and A.G.P./Alliance Global Partners ("A.G.P") entered into the ATM Sales Agreement, pursuant to which the Company may offer and sell, from time to time, at its option, shares of the Common Stock through A.G.P, as sales agent, in an "at the market offering" as defined in Rule 415(a)(4) under the Securities Act of 1933, as amended (the "Securities Act"). Sales in the "at the market offering" may occur under the Company's current effective registration statement on Form S-3 (File No. 333 - 255726) which was filed on May 2, 2024 (File No. 333-279077) and declared effective on September 25, 2024, utilizing a prior prospectus and related prospectus supplements thereto or a newly filed registration statement on Form S - 3. In addition, on May 1, 2024, the Company and B. Riley Securities, Inc. mutually agreed to enter into a notice of termination whereby B. Riley Securities, Inc. would no longer be a party to the ATM Sales Agreement. During the year ended December 31, 2025, the Company sold through the Sales Agreement 17,998,117 shares of the Company's Common Stock pursuant to the ATM Sales Agreement and received net proceeds of approximately $6.8 million. During the year ended December 31, 2024, the Company sold through the Sales Agreement approximately 569,000 shares of the Company's Common Stock pursuant to the ATM Sales Agreement and received net proceeds of approximately $3.6 million.

10. Loans payable

As a result of the Acquisition of VCN, the Company acquired interest-free or below-market interest rate loans (0%-1%) extended by Spanish governmental institutions of Ministerio de Ciencia, Innovacion y Universidades (RETOS loan) and ACC10 Generalitat de Catalunya (NEBT loan). The maturities of these loans are between 2024 and 2028. As a result of the Acquisition, the Company maintains a restricted cash collateral account of $46,000 relating to the RETOS loan, which is reflected as a non-current asset on the balance sheet.

During September 2024, the Company announced that its THERICEL project had been awarded €2.28 million (approximately $2.54 million) from the National Knowledge Transfer Program of the Spanish government's Ministry of Science, Innovation & Universities to support a collaboration between the Company and the Universitat Autònoma de Barcelona ("UAB") to advance the Company's THERICEL suspension cell platform for the clinical manufacture of adenovirus- and adeno-associated virus ("AAV") therapies. Under the award, the Company (via its wholly owned subsidiary, Theriva Biologics SL) received an unsecured loan (the "Loan") of €1.3 million (approximately $1.4 million) as a lump sum payment on January 17, 2025 which bears interest at a rate of 4.015% and is to be repaid over 7 years commencing three years from the date of award.

The Company incurred and charged to interest expense $61,000 and $6,000 during the years ended December 31, 2025 and 2024, respectively.

The current and non-current balance of outstanding loans as of December 31, 2025 and 2024 was as follows *(amounts in thousands of dollars)*:

	December 31, 2025 Current	December 31, 2025 Non-current	December 31, 2024 Current	December 31, 2024 Non-current
NEBT Loan	$ 9	$ 9	$ 7	$ 16
RETOS 2015	48	38	54	76
THERICEL Loan	—	1,624	—	—
	$ 57	$ 1,671	$ 61	$ 92

10. Loans payable (continued)

A maturity analysis of the debt as of December 31, 2025 is as follows *(amounts in thousands of dollars)*:

2026	$ 57
2027	36
2028	11
2029	84
2030	232
Thereafter	1,308
Total	$ 1,728

11. Related Party

On December 13, 2024, the Company approved the compensation of MaryAnn Shallcross, the wife of Steven Shallcross, of $157,000, a bonus of $45,000. During the year ended December 31, 2025, the Company had $202,000 in compensation expense related to Ms. Shallcross and the grant of an option to purchase 25,000 shares of Common Stock having a value of $27,000. Ms. Shallcross was one of the seven employees whose employment was terminated in connection with the Company's workforce reduction announced on September 30, 2025.

12. License, Collaborative and Employment Agreements and Commitments

License and Collaborative Agreements

As described below, the Company has entered into several license and collaborative agreements for the right to use research, technology and patents. Some of these license and collaborative agreements may contain milestones. The specific timing of such milestones cannot be predicted and is dependent on future developments as well as regulatory actions which cannot be predicted with certainty (including actions which may never occur). Further, under the terms of certain licensing agreements, the Company may have the obligation to pay certain milestones contingent upon the achievement of specific levels of sales. Due to the long-range nature of such commercial milestone liability amounts, they are neither probable at this time nor predictable and consequently are not recorded in the financial statements or included in this disclosure.

IDIBELL Technology Transfer Agreement

On August 31, 2010, VCN entered into a Technology Transfer Agreement (the "Technology Transfer Agreement") with the Bellvitge Biomedical Research Institute ("IDIBELL") for the exclusive license of the right to use a Spanish patent number P200901201 titled "Oncolytic adenoviruses for treating cancer" which is co-owned by IDIBELL and Catalan Oncology Institute ("ICO") for the term of the patent. The Technology Transfer Agreement provides that IDIBELL is entitled to a low single digit percentage royalty on the income collected by VCN from the utilization of products derived from the licensed technology, prior to applying any value-added tax, if any, and low single digit percentage royalty on other income received by VCN arising from the use of the licensed technology, including income related to sublicenses of the licensed technology to third parties and advance payments or payments made for goals that were met and/or services associated with the licensed technology. The Technology Transfer Agreement terminates upon the expiration of the patent rights and is subject to early termination by either party in the event of a breach by the other party of its obligations thereunder. In addition, IDIBELL has the right to revoke the license if VCN ceases business activities for a continuous year or ceases to utilize the technology subject of the Technology Transfer Agreement, uses the technology in violation of the principals of IDIBELL or ICO or stops maintaining the patent licensed under the Technology Transfer Agreement. No amounts were incurred in 2025 and 2024.

12. License, Collaborative and Employment Agreements and Commitments – (continued)

ICO Marketing License

On May 16, 2009, VCN entered into a Contract to Grant a Marketing License (the "ICO License Agreement") with ICO for a manufacturing and marketing license of a patent P200700665 titled "Adenovirus with mutations in the area of endoplasmic retention of protein E3-19k and their use in the treatment of cancer" in connection with a sublicense identified therein. The validity period of the license granted is unlimited with the only applicable limit being the patent's own validity. The ICO License Agreement provides that the ICO is entitled to a royalty of low double digit percentage of the net value of the income from the concession of the identified sublicense and low double digit percentage on other lump sums received thereunder. VCN and its sublicensees have an obligation to use all diligent and commercially reasonable efforts for the exploitation of the patent, otherwise, ICO may proceed to recover the license. The ICO License Agreement terminates upon the expiration of the patent rights and is subject to early termination by either party in the event of a breach by the other party of its obligations thereunder. No amounts were incurred in 2025 and 2024.

IDIBELL/ICO License Agreement

On March 4, 2016, VCN entered into a License Agreement (the "IDIBELL/ICO License Agreement") with IDIBELL and the ICO, for the exclusive license of the right to use a family of patents whose priority application is European patent application EP 14 38 2162.7 titled "Adenovirus comprising an albumin-binding molety". The License Agreement provides that IDIBELL and ICO, as licensors, are entitled to share a low single digit percentage royalty on the annual Net Sales (as defined in the IDIBELL/ICO License Agreement) collected by VCN from the utilization of products derived from the licensed technology and a royalty on sublicensing income received from the licensed technology at a rate of: low double digit percentage during the first 3 years following the effective date of the agreement, mid single digit percentage during the term of 3 to 7 years following the effective date and low single digit percentage thereafter. The IDIBELL/ICO License Agreement also provides for certain fixed payments, including a payment 25 days following the date of concession of the licensed patent in a minimum of three European jurisdictions and a payment 25 days following the date of concession of an American patent derived from the licensed patent. The IDIBELL/ICO License is for an indefinite term subject to early termination (i) by mutual agreement of the parties; (ii) by licensor in the event of at least two successive breaches or three alternate breaches calculated annually of the obligation to pay any consideration; (iii) by VCN at its discretion due to certain patent infringements of rights protected by the patents or due to the absence of protection of the patent in any countries in the territory which is worldwide or (iv) in the event of a breach by the other party of its obligations thereunder which are not remedied within thirty (30) days. In addition, the licensors have the right to revoke the IDIBELL/ICO License Agreement if VCN during a continuous period of two years abandons its research or development activities of the licensed patent or activities aimed at exploitation of the resulting products, VCN has undertaken no marketing whatsoever during the term of the IDIBELL/ICO License Agreement or uses the patent licensed for purposes other those as set forth in the IDIBELL/ICO License Agreement. No amounts were incurred in 2025 and 2024.

12. License, Collaborative and Employment Agreements and Commitments – (continued)

Sant Joan De Déu Collaboration and License Agreement

On February 15, 2016, VCN entered into a Collaboration Agreement to Conduct a Clinical Trial and Grant an Operating License (the "Collaboration and License Agreement") with the Sant Joan De Déu Hospital (the "Hospital") and the Sant Joan De Déu Foundation (the "Foundation", and together with the Hospital, the "Institution") regarding the conduct of a clinical trial to evaluate the safety and activity of VCN-01 (zabilugene almadenorepvec) in patients with refractory retinoblastoma. The Collaboration and License Agreement provides that if the trial results are positive and VCN is interested in continuing with the development of VCN-01 for the treatment of retinoblastoma; (a) the parties undertake to apply their best efforts to negotiate and, where appropriate, sign an agreement to collaborate in the development and execution of the following phases of the development of VCN-01 for the treatment of retinoblastoma; (b) the Institution shall grant to VCN an exclusive, worldwide and indefinite license to use and exploit the trial results and their possible patents exclusively for the treatment of retinoblastoma; (c) VCN shall pay the Foundation five hundred thousand Euros (€500,000), subject to reduction for any public and/or private economic aid that third parties may grant to the Institution for the conduct of the trial and/or any advance payments made by VCN before the end of the trial; (d) VCN shall pay the Foundation three hundred twenty thousand Euros (€320,000) once following the trial results of a pivotal study, to be carried out by VCN, has been completed which allows it to obtain the marketing authorization of the product following from the results, which payment must be made within a maximum period of four (4) years from the date on which Institution has delivered the final report of the trial to VCN; and (e) the parties will use their best efforts to negotiate and, where appropriate, sign a product supply agreement in order that the Hospital can use VCN-01 for compassionate use in the treatment of retinoblastoma. The Collaboration and License Agreement continues in force and effect until all obligations arising from the trial have been fulfilled, subject to early termination for a material breach by a party of any of their contractual and/or legal obligations, or, in the case of any other type of breach, when the breaching party has been asked in writing to remedy the breach and the breach is not cured within thirty (30) days from the date on which the written request was sent. On April 23, 2024, the Company announced positive topline data from this study, with agreement by the study Monitoring Committee that the study had a positive outcome. Per the terms of the clinical trial agreement, the determination by the study Monitoring Committee that the study had a positive outcome means we received an exclusive, worldwide technology license, and related patents from Hospital Sant Joan de Déu for the treatment of pediatric patients with advanced retinoblastoma and we are obligated to pay to Hospital Sant Joan de Déu the amount of three hundred twenty thousand, two hundred and sixty five Euros (€320,265) or approximately $334,000, half of which was paid during the year ended December 31, 2024 and the remaining half is expected to be paid upon invoice receipt.

On November 2, 2023, after Sant Joan de Déu - Barcelona Children's Hospital determined that the trial results were positive, VCN and Sant Joan de Déu-Barcelona Children's Hospital announced an agreement for an exclusive worldwide option to negotiate an exclusive license of certain Sant Joan de Deu intellectual property rights related to the use of VCN-01 in combination with topoisomerase I inhibitor chemotherapies for the treatment of cancer.

During the year ended December 31, 2023 the Company paid Euros (€25,000) option fee. During the year ended December 31, 2024 the Company paid Euros (€5,000) for a renewal of the option fee. No amounts were incurred in 2025.

Washington University School of Medicine in St. Louis Clinical Trial Agreement

On August 7, 2019, the Company entered into a clinical trial agreement ("CTA") with Washington University School of Medicine in St. Louis ("Washington University") to conduct a Phase 1b/2a single-center, randomized, double-blinded, placebo-controlled clinical trial designed to evaluate the safety, tolerability and pharmacokinetics of oral SYN-004 (ribaxamase) in up to 36 adult allogeneic hematopoietic cell transplant (HCT) recipients (the "Study"). Under the terms of the CTA, the Company will serve as the sponsor of the Study and supply SYN-004 (ribaxamase), as well as compensate Washington University for all research services to be provided in connection with the Study which is estimated to cost approximately $3,200,000. Dr. Erik R. Dubberke, Professor of Medicine and Clinical Director, Transplant Infectious Diseases at Washington University will serve as the principal investigator of the trial in collaboration with his Washington University colleague Dr. Mark A. Schroeder, Associate Professor of Medicine, Division of Oncology, Bone Marrow Transplantation and Leukemia.

12. License, Collaborative and Employment Agreements and Commitments – (continued)

The CTA continues in effect until completion of all obligations under the CTA. Either party may terminate the CTA prior to completion of its obligations (i) if authorization of the study is withdrawn by the FDA; (ii) if the emergence of any adverse reaction or side effect with SYN-004 (ribaxamase) administered in the Study is of such magnitude or incidence in the opinion of either party to support termination; or (iii) upon a breach of the terms of the CTA if the breaching party fails to cure the breach within 30 days after receipt of notice. The Company has the right to terminate the CTA (i) effective immediately if Washington University fails to perform the study in accordance with the terms of the protocol, the CTA or applicable laws or regulations or if Washington University or the principal investigator become debarred or (ii) upon 14 days written notice and Washington University has the right to terminate the CTA upon 14 days notice if the principal investigator becomes unable to perform or complete the Study and the parties have not, prior to the expiration of such fourteen (14) day period, agreed to an alternative principal investigator. There we no payments during 2024 or 2025.

Prev ABR LLC ("Prev") Agreement

On November 28, 2012, the Company entered into an agreement ("Prev Agreement") to acquire the C. diff program assets of Prev, including the pre-Investigational New Drug (IND) package, Phase 1 and Phase 2 clinical data, manufacturing process data and all issued and pending U.S. and international patents. Upon execution and closing of the Prev Agreement, the Company paid Prev cash payments of $235,000 and issued 17,858 unregistered shares of its Common Stock to Prev. As set forth in the Prev Agreement, Prev may be entitled to receive additional consideration upon the achievement of certain milestones, including: (i) commencement of an IND; (ii) commencement of a Phase 1 clinical trial; (iii) commencement of a Phase 2 clinical trial; (iv) commencement of a Phase 3 clinical trial; (v) filing a Biologic License Application (BLA) in the U.S. and for territories outside of the U.S. (as defined in the Prev Agreement); and (vi) approval of a BLA in the U.S. and for territories outside the U.S. With exception of the first milestone payment, the remaining milestones are payable 50% in cash and 50% in the Company's stock, however, at Prev's option the entire milestone may be payable in shares of the Company's stock. As of December 31, 2015, the first three milestones had been met, and at Prev's option, Prev elected to receive 18,724 shares of the Company's Common Stock. Currently, assets licensed under this agreement are used in the Company's Phase 1b/2a Clinical Study in Allogeneic HCT Recipients. No milestones were achieved or such payments were made subsequent to 2015.

Employment Agreements

On March 3, 2025, the Company entered into a two-year employment agreement with Steven A. Shallcross, (the "2025 Shallcross Employment Agreement"), to serve as the Chief Executive Officer and to continue to serve as the Chief Financial Officer of the Company.

The 2025 Shallcross Employment Agreement has a stated term of two years but may be terminated earlier pursuant to its terms. The terms of the 2025 Shallcross Employment Agreement were substantially the same as the terms of the employment agreement previously entered into by and between the Company and Mr. Shallcross on January 3, 2022 except for the stated term. If Mr. Shallcross' employment is terminated for any reason, he or his estate as the case may be, will be entitled to receive the accrued base salary, vacation pay, expense reimbursement and any other entitlements accrued by him to the extent not previously paid (the "Accrued Obligations"); provided, however, that if his employment is terminated (i) by the Company without Cause or by Mr. Shallcross for Good Reason (as each is defined in the 2025 Shallcross Employment Agreement) then in addition to paying the Accrued Obligations, (a) the Company will continue to pay his then current base salary and continue to provide benefits at least equal to those that were provided at the time of termination for a period of twelve (12) months and (b) he shall have the right to exercise any vested equity awards until the earlier of six (6) months after termination or the remaining term of the awards; or (ii) by reason of his death or Disability (as defined in the 2025 Shallcross Employment Agreement), then in addition to paying the Accrued Obligations, Mr. Shallcross would have the right to exercise any vested options until the earlier of six (6) months after termination or the remaining term of the awards. In such event, if Mr. Shallcross commenced employment with another employer and becomes eligible to receive medical or other welfare benefits under another employer-provided plan, the medical and other welfare benefits to be provided by the Company as described herein would terminate.

12. License, Collaborative and Employment Agreements and Commitments – (continued)

The 2025 Shallcross Employment Agreement provides that upon the closing of a "Change in Control" (as defined in the 2025 Shallcross Employment Agreements), all unvested options shall immediately vest and the time period that Mr. Shallcross will have to exercise all vested stock options and other awards that Mr. Shallcross may have will be equal to the shorter of: (i) eighteen (18) months after termination, or (ii) the remaining term of the award(s). If within one (1) year after the occurrence of a Change in Control, Mr. Shallcross terminates his employment for "Good Reason" or we terminate Mr. Shallcross's employment for any reason other than death, disability or Cause, Mr. Shallcross will be entitled to receive: (i) the portion of his base salary for periods prior to the effective date of termination accrued but unpaid (if any); (ii) all unreimbursed expenses (if any); (iii) an aggregate amount (the "Change in Control Severance Amount") equal to two (2) times the sum of his base salary plus an amount equal to the bonus that would be payable if the "target" level performance were achieved under the Company's annual bonus plan (if any) in respect of the fiscal year during which the termination occurs (or the prior fiscal year if bonus levels have not yet been established for the year of termination) subject to him executing a general release in form acceptable to us that becomes effective. If within two (2) years after the occurrence of a Change in Control, Mr. Shallcross terminates his employment for "Good Reason" or the Company terminates Mr. Shallcross's employment for any reason other than death, disability or Cause, Mr. Shallcross will be entitled to also receive for the period of two (2) consecutive years commencing on the date of such termination of his employment, medical, dental, life and disability insurance coverage for him and the members of his family that are not less favorable to him than the group medical, dental, life and disability insurance coverage carried by the Company for him subject to him executing a general release in form acceptable to the Company that becomes effective. The Change in Control Severance Amount is to be paid in a lump sum if the Change in Control event constitutes a "change in the ownership" or a "change in the effective control" of the Company or a "change in the ownership of a substantial portion of a corporation's assets" (each within the meaning of Section 409A of the Internal Revenue Code ("Rule 409A")), or in 48 substantially equal payments, if the Change in Control event does not so comply with Section 409A.

On December 13, 2024, the Board of Directors of the Company awarded Steven A. Shallcross a cash bonus equal to $200,000. In addition, on December 14, 2023, the Company increased his base salary to $667,536 due to a merit increase.

On April 28, 2025, Mr. Shallcross was awarded options to purchase 190,000 shares of the Company's Common Stock.

Operating Lease

The Company's existing leases as of December 31, 2025 for its U.S. and Spanish facilities are classified as operating leases. During the quarter ended June 30, 2021, the Company renewed its Rockville, MD facility lease by entering into a Second Lease Amendment which extends the lease term for 63 months beginning on September 1, 2022 and ending on December 31, 2027 at stated rental rates and including a 3-month rent abatement. The Second Amendment also has options for a Tenant Improvement Allowance and a Second Extension Term. The Second Extension Term is offered at market rates and there is no economic incentive for the lessee, therefore the Company has determined that it is not part of the original lease term.

12. License, Collaborative and Employment Agreements and Commitments – (continued)

The Company also leases research and office facilities in Barcelona, Spain for its 100 percent owned Theriva S.L. subsidiary. On the closing date of the Acquisition, a sublease was executed for Theriva S.L. to lease research and office facilities at a new location in Parets del Valles (Barcelona) from the former owner of Theriva S.L. This lease was executed for an initial term to begin in January 2023 until October 2026, with an option to renew for an additional five years. On January 15, 2023, Theriva S.L. moved into the facilities and the new lease commenced and the prior lease terminated.

Operating lease costs are presented as part of general and administrative expenses in the consolidated statements of operations, and for the year ended December 31, 2025 and 2024 approximated $656,000 and $631,000, respectively. For the Barcelona lease, the day one non-cash addition of right of use assets due to adoption of ASC 842 was $937,000. For the years ended December 31, 2025 and 2024, cash paid for amounts included in the measurement of operating liabilities was $696,000 and $661,000, respectively. As of December 31, 2025 and 2024, the weighted-average remaining lease term for the Company's leases was 1.7 and 2.6 years, respectively. As of December 31, 2025 and 2024, the weighted-average discount rate for the Company's leases was 9.93% and 10.42%, respectively.

A maturity analysis of the Company's operating leases as of December 31, 2025 is as follows *(amounts in thousands of dollars)*:

Future undiscounted cash flow for the years ending December 31,	
2026	605
2027	368
Total	973
Discount factor	(72)
Operating lease liability	901
Operating lease liability - current	(549)
Operating lease liability - long term	$ 352

Consulting Fees

In November 2017, the Company engaged a regulatory consultant to assist in the Company's efforts to prepare, file and obtain FDA approval for ribaxamase. The term of the engagement is on a monthly basis, provided that either party may terminate the agreement at any time by providing the other party a six-month notice period. The Company was obligated to pay the consultant a monthly retainer in addition to success fee payments of up to an aggregate of $4,500,000 for attainment of certain regulatory milestones. The Company believes that achievement of the milestones is not probable at this time. No amounts incurred in 2025 and 2024.

Risks and Uncertainties

The uncertain financial markets, disruptions in supply chains, mobility restraints, and changing priorities as well as volatile asset values could impact the Company's business in the future. The Company and its third-party contract manufacturers, contract research organizations, and clinical sites may also face disruptions in procuring items that are essential to the Company's research and development activities, including, for example, medical and laboratory supplies used in its clinical trials or preclinical studies, in each case, that are sourced from abroad or for which there are shortages. Further, although the Company has not experienced any material adverse effects on business due to increasing inflation, it has raised operating costs for many businesses and, in the future, could impact demand or pricing manufacturing of its drug candidates or services providers, foreign exchange rates or employee wages. The Company is actively monitoring the effects that these disruptions and increasing inflation could have on its operations.

12. License, Collaborative and Employment Agreements and Commitments – (continued)

Through the VCN Acquisition, the Company has operations in Spain related to conducting research and development, manufacturing, and clinical trials in Western European countries. The invasion of Ukraine by Russia, the war in the Middle East, and the retaliatory measures that have been taken, or could be taken in the future, by the United States, NATO, and other countries have created global security concerns that could result in a regional conflict and otherwise have a lasting impact on regional and global economies, any or all of which could disrupt the Company's supply chain, and despite the fact that it currently does not plan any clinical trials in Eastern Europe, may adversely impact the cost and conduct of R&D, manufacturing, and international clinical trials of its product candidates.

13. Income Taxes

Effective January 1, 2025, we adopted the new income tax disclosure standard (Income Taxes (Topic 740): Improvements to Income Tax Disclosures) on a prospective basis. Accordingly, the tables presenting our income tax provision and effective tax rate reconciliation will reflect the new standard for 2025, while the 2024 disclosures will continue to follow the previous disclosure requirements.

Losses before income taxes for the years ended December 31, 2025 and 2024 was as follows:

	Year Ended December 31,	
	2025	2024
Domestic	$ (15,020)	$ (7,641)
Foreign	(8,719)	(18,012)
Income/(Loss) before Income Taxes	$ (23,739)	$ (25,653)

The components of income tax benefit consisted of the following for the years ended December 31, 2024 and 2023:

	Year Ended December 31,	
	2025	2024
Current:		
Federal	$ —	$ —
State	—	—
Foreign	—	—
Total Current	—	—
Deferred:		
Federal	$ —	$ —
State	—	—
Foreign	—	—
Total Deferred	—	—
Provision (Benefit) for income taxes	—	—

13. Income Taxes – (continued)

Income tax provision (benefit) related to continuing operations differ from the amounts computed by applying the statutory income tax rate of 21% to pretax loss as follows (in thousands):

	Year Ended December 31, 2025		Year Ended December 31, 2024	
	Amount	Rate	Amount	Rate
US Federal Statutory Tax Rate	$ (4,985)	21.00 %	(5,387)	21.00 %
State and Local Income Taxes, Net of Federal Income Tax Effect	—	— %	—	— %
Changes in Valuation Allowances	(1,096)	4.62 %	(14,902)	58.09 %
Nontaxable or Nondeductible Items				
Fair Value–Contingent Consideration	1,897	(7.99)%	147	(0.57)%
Other Nontaxable or Nondeductible amounts	82	(0.34)%	75	(0.29)%
Other Adjustments				
Temporary difference true-ups	438	(1.85)%	181	(0.71)%
Section 382 limitation	1,834	(7.72)%	16,103	(62.77)%
Foreign Tax Effects-Spain				
VCN Impairment	(1,442)	6.07 %	1,400	(5.46)%
Return to Provision book loss	1,773	(7.47)%	(1)	— %
Statutory tax rate difference between Spain and United States	(349)	1.47 %	(721)	2.81 %
Changes in Valuation Allowances	1,847	(7.78)%	3,741	(14.58)%
NOL adjustment- 382 study	—	— %	(637)	2.48 %
Other Adjustments	1	(0.01)%	1	— %
Effective Tax Rate	**$** —	— %	—	— %

13. Income Taxes – (continued)

Deferred Tax Assets and Liabilities

Deferred income taxes reflect the net tax effects of loss and credit carry forwards and temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets for federal and state income taxes are as follows (in thousands):

	Year Ended December 31,	
	2025	2024
Deferred Tax Assets:		
Federal, State and Foreign NOL Carryforward	$ 13,044	$ 9,714
Accrued Compensation	80	26
Stock Issued For Services	409	785
Stock Issued for Acquisition of Program	1,217	1,398
Stock Issued for License Agreement	649	888
Amortizable License Fee	2	3
ASC 842 Lease Liability	161	231
Other Deferred Tax Asset	314	11
Capitalized Research & Development costs	2,108	2,885
Total Gross DTA	17,984	15,941
Less: Valuation Allowance	(12,537)	(11,326)
Total Deferred Tax Assets	5,447	4,615
Deferred Tax Liabilities:		
IPR&D	(5,253)	(4,340)
ASC 842 ROU Asset	(194)	(275)
Total Gross DTL	(5,447)	(4,615)
Net Deferred Tax Asset (Liability)	**$** —	**$** —

On March 10, 2022, the Company acquired VCN, a Spanish Company in a tax-free stock acquisition. Due to this acquisition, VCN is a wholly owned subsidiary of the company. As a result of the acquisition, a deferred tax liability was established with purchase accounting related to acquired In Process Research and Development. A deferred tax asset was also established with purchase accounting related to VCN's unlimited life net operating loss carryover. During 2024, for book purposes, IPR&D and Goodwill assets were both impaired, with Goodwill written down to zero and IPR&D written down to $17.4 million. The impairment to Goodwill represents a permanent difference and the impairment to IPR&D represents a reduction in the deferred tax liability established with the Company's VCN acquisition.

At December 31, 2025, the Company has a gross Federal net operating loss carry-forward of approximately $1.5 million available to offset future United States taxable income. In 2024 and 2025, it was determined that availability of gross Federal net operating losses of $76.7 million and $1.8 million respectfully were fully limited as well as $7.4 million of current 2025 net operating losses as a result of change of ownership that occurred in 2025 under Section 382 of the Internal Revenue Code. State Net Operating Losses are also limited by Section 382 of the Internal Revenue Code and were limited accordingly. At December 31, 2024, the Company has a gross Foreign net operating loss carry forward of approximately $43.0 million USD. The foreign net operating loss carries forward indefinitely.

13. Income Taxes – (continued)

In 2020, the Company completed an Internal Revenue Code Section 382 analysis of its historical net operating loss carry-forward amount. As a result, the prior year net operating loss carry-forward was limited by $155.6 million. The decrease in the prior year net operating loss is attributable to control ownership changes which were determined for the years 2013 and 2018 which caused the reduction in the value of the historical net operating loss carry-forward amounts. Updated section 382 analysis were performed in 2021, 2022, 2023 and 2024 to identify if any additional ownership shifts occurred in these years. It was determined that an ownership shift occurred in January 2021 and in September 2024. The result of the updated Section 382 analysis produced an IRC 382 limit due to the 2021 and 2024 ownership changes. There was no ownership change determined for 2022 or 2023. In 2025 it was determined that all of the Company's Federal and state Net Operating Loss carry forwards through 12/31/2024 as well as a portion of the current year 2025 loss were limited due to an updated 382 study performed in 2025.

As a result the of 2025 section 382 study, the Company's does not have any pre-2018 net operating losses available for use in future tax years. In addition, all post 2017 net operating losses through 12/31/2024 are also not available due the section 382 study. $1.5 million of the net operating loss carry-forward originating in 2025 is not subject to additional limitations based on taxable income as of December 31, 2025.

The Company's valuation allowance at December 31, 2025 was approximately $12.5 million. The net change in valuation allowance during the year ended December 31, 2025, was an increase of $1.2 million due to the following; $(.1) million federal and state net operating loss related to 382 limitation, an increase in foreign net operating loss of $3.4. offset by decreases in domestic and foreign deferred tax assets of $(1.2) and $(.9) million. In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred income tax assets will not be realized. The ultimate realization of deferred income tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred income tax liabilities, projected future taxable income, and tax planning strategies in making this assessment. As of December 31, 2025 and 2024, management has established a full valuation allowance against its net deferred tax assets in all US tax jurisdictions. The Company has also established a valuation allowance in its Spanish tax jurisdictions as it is no longer in a net deferred tax liability position in Spain.

As required under ASU 2023-09, the Company has included only the portion of the valuation allowance related to federal deferred tax assets in the "change in valuation allowance" line of the rate reconciliation. The following table presents a reconciliation of the total change in the valuation allowance (in thousands):

	Year Ended December 31,	
	2025	2024
Beginning Balance	$ 11,326	$ 28,351
Change charged to income tax expense	483	(16,788)
Changes charged to OCI	728	(237)
Ending Balance	12,537	11,326

Undistributed earnings of the Company's foreign subsidiary, VCN, are considered to be permanently reinvested and, accordingly, no deferred U.S. income taxes have been provided thereon. Upon distribution of any earnings in the form of dividends or otherwise, those earnings would be subject to U.S. income tax. At the present time, VCN does not have any earnings and thus it is not necessary to estimate the amount of U.S. income taxes that might be payable if these earnings were repatriated.

We have incurred net operating losses since inception, and we do not have any significant unrecognized tax benefits.

14. Subsequent Events

On February 17, 2026 the Company entered into a license agreement (the "Rasayana Agreement") with Rasayana Therapeutics, Inc. ("Rasayana"), whereby the Company granted Rasayana an exclusive worldwide license with the right to grant sublicenses to Research, Develop, Manufacture and Commercialize (as such terms are defined in the Rasayana License Agreement) any Product (as such term is defined in the Rasayana License Agreement), which includes SYN-020, an oral formulation of the recombinant intestinal alkaline phosphatase enzyme, comprising, containing, or covered by the Licensed IP (as such term is defined in the Rasayana License Agreement) and/or devised, developed, or produced using the Licensed IP. Pursuant to the terms of the Rasayana License Agreement, Rasayana will assume all responsibility and costs for the Development and Commercialization of the Products.

Under the terms of the Rasayana License Agreement, the Company received an upfront payment of Three Hundred Thousand Dollars ($300,000) from Rasayana on the effective date of the Rasayana License Agreement. In addition, the Company is entitled to receive from Rasayana development milestone payments of up to an aggregate of $16,000,000 and sales milestone payments of up to an aggregate of $22,000,000 upon achievement of certain development and net sales milestones with respect to Products.

In addition, during the Royalty Term (as such term is defined in the Rasayana License Agreement), the Company is entitled to receive tiered royalties ranging from low to mid single digits on net sales of a Product.

The Company will also be entitled to receive a certain percentage of any Sublicense Revenue (as such term is defined in the Rasayana License Agreement) received by Rasayana or its affiliates.

Under the terms and conditions of the Rasayana License Agreement, Rasayana has agreed to use Commercially Reasonable Efforts (as such term is defined in the Rasayana License Agreement) to meet certain specified Development milestones.

The term of the Rasayana License Agreement commenced on the effective Date and continues on a country-by-country basis until the expiration of the Royalty Term. If either the Company or Rasayana materially breaches any material obligation under the Rasayana License Agreement and does not cure such breach, the non-breaching party may terminate the Rasayana License Agreement in its entirety; provided that if such breach is capable of being cured but cannot be cured within such sixty (60) day period and the breaching party initiates actions to cure such breach within such period and thereafter diligently pursues such actions, the breaching party shall have one additional period of sixty (60) days to cure such breach.. Either party may also terminate the Rasayana License Agreement, upon written notice, if the other party has an Insolvency Event (as such term is defined in the Agreement). Rasayana has the right to terminate the Rasayana License Agreement for any or no reason upon ninety (90) days' written notice to the Company, including but not limited to instances in which the outcome of a clinical trial is adverse and/or unsatisfactory to Rasayana (in its reasonable discretion). If Rasayana suspends all material Development efforts with respect to all Products for a period of one hundred and eighty (180) days, or fails to use Commercially Reasonable Efforts to achieve any of the Development milestones by the applicable deadline), then the Company may terminate the Rasayana Agreement upon ninety (90) days prior written notice to Rasayana, unless Rasayana resumes material Development efforts within such period. Upon a termination the rights granted under the Rasayana License Agreement terminate and revert irrevocably to the Company.

On January 22, 2026, the Company received $1.6 million for the 2024 Research and Development rebate program sponsored by the Spanish government. The program provides for reimbursement of certain expenses incurred in research and development efforts the Company incurs in Spain. The reimbursements can be through either tax credits or direct refunds.

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 adopted and maintain disclosure controls and procedures that are designed to provide reasonable assurance that information required to be disclosed in the reports filed under the Exchange Act, such as this Annual Report on Form 10-K, is collected, recorded, processed, summarized and reported within the time periods specified under the rules of the SEC. Our disclosure controls and procedures are also designed to ensure that such information is accumulated and communicated to management to allow timely decisions regarding required disclosure. As required under Exchange Act Rule 13a-15, our management, including the Chief Executive Officer who also serves as our Chief Financial Officer, evaluated the effectiveness of disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) as of the end of the period covered by this Annual Report on Form 10-K. Our Chief Executive Officer who also serves as our Chief Financial Officer concluded that, as of the end of the period covered by this report, our disclosure controls and procedures were effective.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Exchange Act Rule 13a-15. Internal control over financial reporting is defined in Rule 13a-15(f) and 15(d)-15(f) under the Exchange Act as a process designed to provide reasonable assurance to our management and Board of Directors regarding the preparation and fair presentation of published financial statements. Management conducted an assessment of our internal control over financial reporting as of December 31, 2025 based on the framework and criteria established by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control-Integrated Framework (2013). Based on the assessment, management concluded that, as of December 31, 2025, our internal control over financial reporting was effective.

Our management, including our Chief Executive Officer who is also our Chief Financial Officer, does not expect that our disclosure controls and procedures and our internal control processes will prevent all errors or fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, 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. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of error or fraud, if any, within our 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. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. The design of any system of controls also is based in part upon 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. Over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and may not be detected. However, these inherent limitations are known features of the financial reporting process. Therefore, it is possible to design into the process safeguards to reduce, though not eliminate, this risk.

Changes in Internal Control Over Financial Reporting

During the quarter ended December 31, 2025, there have been no other changes in the Company's internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

Item 9B. ***Other Information.***

Insider Trading Arrangements

During the three months ended December 31, 2025, no director or officer of the Company adopted or terminated a "Rule 10b5-1 trading arrangement" or "nonRule 10b5-1 trading arrangement," as each term is defined in Item 408(a) 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.***

Below is certain information regarding our directors and executive officers.

Name	Age	Position
Steven A. Shallcross	64	Chief Executive Officer, Chief Financial Officer and Director
Jeffrey J. Kraws	61	Chairman
John Monahan	79	Director
Jeffrey Wolf, J.D.	62	Director

Steven A. Shallcross. Mr. Shallcross has been a member of our Board of Directors since December 6, 2018 and currently serves as our Chief Executive Officer, a position he was appointed to on December 6, 2018, and our Chief Financial Officer. Mr. Shallcross was appointed as our Interim Chief Executive Officer on December 5, 2017 and has served as our Chief Financial Officer since joining us in June 2015. Mr. Shallcross brings to our company operational, financial and international biotech industry experience, as well as an established track record at leading the financial development and strategy for several publicly traded biotech companies. From May 2013 through May 2015, Mr. Shallcross served as Executive Vice President and Chief Financial Officer of Nuo Therapeutics, Inc. (formerly Cytomedix, Inc.). In January 2016, Nuo Therapeutics, Inc. filed a voluntary petition for relief under Chapter 11 of the U.S. Bankruptcy Code in the United States Bankruptcy Court for the District of Delaware and on April 25, 2016, the Bankruptcy Court entered an order granting approval of Nuo's plan of reorganization. From July 2012 to May 2013, Mr. Shallcross held the offices of Executive Vice President, Chief Financial Officer and Treasurer of Empire Petroleum Partners, LLC, a motor fuel distribution company. From July 2011 to March 2012, Mr. Shallcross was Acting Chief Financial Officer of Senseonics, a privately-held medical device company located in Germantown, MD. From January 2009 to March 2011, he served as Executive Vice President and Chief Financial Officer of Innocoll AG (formerly privately held Innocoll Holdings, Inc.), a global, commercial-stage biopharmaceutical company specializing in the development and commercialization of collagen-based products. He also served for four years as the Chief Financial Officer and Treasurer of Vanda Pharmaceuticals, Inc., leading the company through its successful IPO and follow-on offering and previously served as the Senior Vice President and Chief Financial Officer of Middlebrook Pharmaceuticals, Inc. (formerly Advancis Pharmaceutical Corporation). In addition, Mr. Shallcross also served as the Chief Financial Officer of Bering Truck Corporation. From June 2019 until March 2024, Mr. Shallcross served on the board of directors of Elys Game Technology, Corp. a Nasdaq listed international, vertically integrated commercial-stage company engaged in various aspects of the leisure gaming industry and from April 2021 until June 2022, he served on the board of directors of TwinVee Powercats, Co., a designer, manufacturer and marketer of recreational and commercial power catamaran boats. He holds an MBA from the University of Chicago's Booth School of Business, a Bachelor of Science degree in Accounting from the University of Illinois, Chicago, and is a Certified Public Accountant in the State of Illinois.

Mr. Shallcross brings to the Board of Directors significant strategic, business and financial experience related to the business and financial issues facing biotechnology companies. Mr. Shallcross has a broad understanding of the financial markets, financial statements as well as generally accepted accounting principles. Through his services as our Chief Executive Officer and Chief Financial Officer, he has developed extensive knowledge of our business.

Jeffrey J. Kraws. Mr. Kraws has been a member of the Company's Board of Directors since January of 2006, and was appointed independent, non-executive Chairman of the Board in May 2012. Since 2003, Mr. Kraws has served as Chief Executive Officer and co-founder of Crystal Research Associates and CRA Advisors, and since February 2012, he has served as partner and co-founder of TopHat Capital, LLC. In February 2026, Mr. Kraws joined Kazia Therapeutics Limited as the Head of Corporate Strategy and Development. From February 2022 to January 2025, Mr. Kraws served as Chief Financial Officer of Syncromune, Inc. Mr. Kraws served as the Chief Executive Officer of Innovational Biotech Inc., formerly known as GridIron Bionutrients, Inc., from November 2021 through December 2022. From August 2016 through January 2021, Mr. Kraws served as the Co-President of Ra Medical Systems Inc. (NYSE: RMED), a medical device company. Mr. Kraws has served as a partner at Grannus Securities Pty Ltd. (an Australian based private equity fund) since November 2015. Mr. Kraws is also a partner of PDK Healthcare Innovations LLC. He also consults and assists in management of private companies through his private practice. Mr. Kraws has received some of the most prestigious awards in the industry. Among other awards, he was given a "5-Star Rating" in 2001 by Zacks and was ranked the number one analyst among all pharmaceutical analysts for stock performance in 2001 by Starmine.com. Prior to founding Crystal Research Associates, Mr. Kraws served as co-president of The Investor Relations Group (IRG), a firm representing primarily under-followed, small-capitalization companies. Previously, Mr. Kraws served as a managing director of healthcare research for Ryan Beck & Co. and as director of research/senior pharmaceutical analyst and managing director at Gruntal & Co., LLC (prior to its merger with Ryan Beck & Company). Mr. Kraws served as managing director of the healthcare research group and senior pharmaceutical analyst at First Union Securities (formerly EVEREN Securities); as senior U.S. pharmaceutical analyst for the Swedish-Swiss conglomerate Asea Brown Boveri; and as managing director and president of the Brokerage/Investment Banking operation of ABB Aros Securities, Inc. He also served as senior pharmaceutical analyst at Nationsbanc Montgomery Securities, BT Alex Brown & Sons, and Buckingham Research. Mr. Kraws also has industry experience, having been responsible for competitive analysis within the treasury group at Bristol-Myers-Squibb Company. During 2006 through February of 2007, Mr. Kraws served as our Vice President of Business Development, on a part-time basis. Since December 2013 until April 2023, Mr. Kraws served on the board of directors of Avivagen Inc. (TSX:VIV) and from 2013 until 2020 served on the board of directors of Saleen Automotive, Inc. (OTC Pink: SLNN). He holds an M.B.A. from Cornell University and a B.S. degree from State University of New York — Buffalo. Mr. Kraws brings a strong business background to us, having worked as a pharmaceutical analyst for over 35 years.

Mr. Kraws brings to the Board of Directors significant strategic, business and financial experience related to the business and financial issues facing pharmaceutical companies. Mr. Kraws has a broad understanding of the operational, financial and strategic issues facing pharmaceutical companies. His healthcare experience, executive and leadership experience further qualify him as a member of the Board.

John Monahan. Dr. Monahan has been a member of the Company's Board of Directors since November 11, 2020. Dr. Monahan has served on the board of directors of Scorpius Holdings, Inc. since November 2009 (formerly known as NightHawk Biosciences, Inc.), a publicly traded company, and from August 2016 until May 2021 also served on the board of directors of Anixa Biosciences, Inc. (formerly known as ITUS Corporation), a biotechnology company focused on using the body's immune system to diagnose, treat and prevent cancer. He is also a board member of Cellix Ltd. (Ireland) and has served on a number of other public and private boards over the years. Dr. Monahan co-founded Avigen Inc. in 1992, a company which has become a leader in its sector for the development of novel pharmaceutical products for the treatment of serious human diseases. Over a 12-year period as Chief Executive Officer of Avigen he raised over $235 million in several private and public financings including its initial public offering. From 1989-1992, he was Vice President of Research & Development at Somatix Therapy Corp., Alameda, CA and from 1985-1989 he was Director of Molecular & Cell Biology at Triton Biosciences Inc., Alameda, CA. Prior to that from 1982-1985, he was Research Group Chief, Department of Molecular Genetics, Hoffmann-LaRoche, Inc. Nutley, NJ, and from 1975 to 1977 he was an Instructor at Baylor College of Medicine, Houston TX. Dr. Monahan served as a scientific advisory consultant to the Company from 2015 to November 10, 2020 and from 2010 through 2015 he was the Company's Senior Executive Vice President of Research & Development. Dr. Monahan was also a Scientific Advisory Board member of Agilis Biotherapeutics (recently merged into PTC Therapeutics), from 2014 to 2019. Dr. Monahan received his Ph.D. in Biochemistry from McMaster University, Canada and his B.Sc. from University College Dublin, Ireland.

Dr. Monahan brings to our Board of Directors significant knowledge of and experience in the pharmaceutical and medical industries. He has extensive business, managerial, executive and leadership experience that further qualify him to serve as a member of the Board and a valuable understanding of biochemistry and our product candidates.

Jeffrey Wolf, J.D. Mr. Wolf, who has been a member of the Company's Board of Directors since 2006, has substantial experience in creating, financing, nurturing and biomedical ventures based upon breakthrough research and technology. In August 2008, Mr. Wolf founded Scorpius Holdings, Inc. (formerly known as NightHawk Biosciences, Inc.), a publicly traded company. Since April 2010, Mr. Wolf has served as the Chief Executive Officer and Chairman of the Board of Scorpius Holdings, Inc. Prior to founding Scorpius Holdings, Inc., from June 1997 to March 2011, Mr. Wolf served as managing director at Seed-One Ventures, LLC a venture firm focused on launching and growing exceptional healthcare companies from the ground up. Mr. Wolf has also founded and run several biomedical companies. Mr. Wolf's start-ups include Avigen, a San Francisco-based gene therapy company where he was a co-founder and director; TyRx Pharma, a company focused on the development of bio-compatible polymers where he was a co-founder and Chairman; and Elusys Therapeutics, a company focused on the development of ANTHIM, an FDA approved antitoxin against anthrax, which is currently a subsidiary of NightHawk. Mr. Wolf received his MBA from Stanford Business School, his J.D. from New York University School of Law and his B.A. from the University of Chicago, where he graduated with honors in Economics.

Mr. Wolf has extensive knowledge of the industry and in particular research and development. His legal and business background provide him with a broad understanding of the legal, operational, financial and strategic issues facing our company. Having served as a board member on other public company boards, Mr. Wolf has an extensive understanding of the operational, financial and strategic issues facing public companies.

Family Relationships

There are no family relationships among any of our directors and executive officers.

Involvement in Certain Legal Proceedings

To our knowledge, there are currently no legal proceedings, and during the past ten years there have been no legal proceedings, involving our executive officers, directors or persons nominated to become a director that we believe are required to be disclose pursuant to Item 4.01(f) of Regulation S-K.

Directors' Term of Office

Directors will hold office until the next annual meeting of stockholders and the election and qualification of their successors. Officers are elected annually by our Board of Directors and serve at the discretion of the Board of Directors.

Audit Committee

The Audit Committee is comprised of Mr. Wolf (Chairman), Mr. Kraws and Dr. Monahan. The Audit Committee is responsible for recommending our independent public accounting firm and reviewing management's actions in matters relating to audit functions. The Committee reviews with our independent public accountants the scope and results of the audit engagement and the system of internal controls and procedures. The Committee also reviews the effectiveness of procedures intended to prevent violations of laws. The Committee also reviews, prior to publication, our reports on Form 10-K and Form 10-Q. Our Board has determined that all audit committee members are independent under applicable SEC regulations and NYSE American rules. Our Board of Directors has determined that each of Mr. Wolf and Mr. Kraws qualify as "audit committee financial experts" as that term is used in Section 407 of Regulation S-K. Our Audit Committee charter is located on our website *www.therivabio.com*.

Compensation Committee

Our Compensation Committee consists of Mr. Kraws (Chairman), Dr. Monahan and Mr. Wolf. This Committee performs several functions, including reviewing all forms of compensation provided to our executive officers, directors, consultants and employees, including stock compensation. Our Board has determined that all compensation committee members are independent under applicable SEC regulations and NYSE American rules. Our Compensation Committee charter is located on our website *www.therivabio.com*.

Nominations Committee

Our Nominations Committee consists of Dr. Monahan (Chairman), Mr. Kraws and Mr. Wolf. This Committee performs several functions, including identifying qualified individuals to become members of the Board and recommending appointments to the Board and appointment of executive officers. The committee seeks individuals who have an inquisitive and objective perspective, practical wisdom and mature judgment, and the talent and expertise to understand and provide sound and prudent guidance with respect to our activities, operations and interests. Candidates must also be individuals who have the highest personal and professional integrity, who have demonstrated exceptional ability and judgment, and who are likely to be the most effective, in conjunction with the other members of the Board, in collectively serving the long-term interests of stockholders. Our Board has determined that all nominations committee members are independent under applicable SEC regulations and NYSE American rules. Our Nominations Committee charter is located on our website *www.therivabio.com*.

Code of Ethics

We have long maintained a Code of Conduct which is applicable to all of our directors, officers and employees. In addition, we have adopted a Code of Ethics for Financial Management which applies to our Chief Executive Officer, Chief Financial Officer, Treasurer and Controller. Each of these codes is posted on our website at *www.therivabio.com*.

Insider Trading Policy

We have adopted an insider trading policy (the "Trading Policy") that is designed to promote compliance with federal securities laws, rules and regulations, as well as the rules and regulations of NYSE American. The Trading Policy was implemented to assure compliance with the securities laws prohibiting insider trading in our securities and disclosure of material, non-public information to outsiders. It prohibits the purchase and sale of our securities by us, our directors, officers, and employees, as well as members of their households, while in possession of material, non-public information until the third business day after such information is made available to the public. Additionally, our Trading Policy imposes special additional trading restrictions, including requiring pre-clearance of any transaction and prohibiting the purchase or sale of options to sell or buy our securities and short sales. The Trading Policy is incorporated by reference into this Annual Report.

Item 11. ***Executive Compensation.***

We are a "smaller reporting company" and the following compensation disclosure is intended to comply with the requirements applicable to smaller reporting companies. Although the rules allow us to provide less detail about our executive compensation program, the Compensation Committee is committed to providing the information necessary to help stockholders understand its executive compensation-related decisions. Accordingly, this section includes supplemental narratives that describe the 2025 executive compensation program for our Named Executive Officer.

The following table summarizes all compensation awarded to, earned by or paid to our Named Executive Officer, Steven A. Shallcross, during the fiscal years presented below.

Name and Principal Position	Year	Salary ($)[1]	Bonus ($)[2]	Options Awards ($)[3]	All Other Compensation ($)[4]	Total ($)
Steven Shallcross	2025	$ 667,536	$ —	$ 201,940	$ 33,535	$ 903,011 [5]
Chief Executive Officer	2024	$ 644,963	$ 200,000	$ —	$ 31,350	$ 876,313 [5]
and Chief Financial Officer						

(1) Mr. Shallcross' annual salary was $644,963 commencing January 1, 2024 and $667,536 commencing January 1, 2025.

(2) Amounts represent annual cash bonuses earned for the applicable fiscal year. The annual cash bonuses are paid in the first quarter of the calendar year following the year to which the cash bonus relates.

(3) Amount reflects the grant date fair value of the Named Executive Officer's stock options, calculated in accordance with FASB ASC Topic 718. For a discussion of the assumptions used in calculating these values, see Note 7 to our consolidated financial statements included elsewhere in this Annual Report. In April 2025, Mr. Shallcross was issued options to purchase 190,000 shares of Common Stock. There were no options issued to the Named Executive Officer during 2024.

(4) The all other compensation column is comprised of vacation accrual paid, and the portion of medical, dental and vision premiums paid by us on behalf of our Named Executive Officer. These benefits are offered to all Theriva Biologics' employees who work at least 17.5 hours per week.

(5) Amounts for the year ended December 31, 2025 and 2024 exclude the following compensation paid to the wife of Mr. Shallcross during the specified years: (i)salary of $157,000 and 152,000 paid in the years ended December 31, 2025 and 2024, respectively, (ii) a bonus of $45,000 during the year ended December 31, 2024, and (iii) an option to purchase 25,000 shares of Common Stock having a value of $27,000 granted during the year ended December 31, 2025.

Narrative Disclosure to Summary Compensation Table

Overview of Our Compensation Program

A. Philosophy and Objectives

The Compensation Committee seeks to attract and retain superior executive talent by offering competitive base salaries, bonuses and long-term incentives. The Compensation Committee's philosophy is to deliver higher rewards for superior performance and consequences for underperformance. It is also the Compensation Committee's practice to provide a balanced mix of cash and equity-based compensation that aligns both the short and long-term interests of our executives with that of our stockholders. Our executive compensation program is based on the following philosophies and objectives:

- Compensation Should Align with Stockholders' Interests — The Compensation Committee believes that executives' interests should be aligned with those of the stockholders. In years other than 2024, executives were granted stock options so that their total compensation was tied directly to value realized by our stockholders. Executive bonuses are tied directly to the achievement of performance goals that the Compensation Committee believes will ultimately drive stockholder value creation.

- Compensation is Competitive — The Compensation Committee seeks to provide a total compensation package that attracts, motivates and retains the executive talent that we need in order to maximize our return to stockholders. To accomplish this objective, executive compensation is reviewed annually to ensure that compensation levels are competitive and reasonable relative to our level of performance and to the compensation opportunities provided by comparable companies with which we compete for talent.

- Compensation Motivates and Rewards the Achievement of Goals — Our executive compensation program is designed to appropriately reward both individual and collective performance that meets and exceeds our annual, long-term and strategic goals. To accomplish this objective, a substantial percentage of total compensation is variable and "at risk," both through annual incentive compensation in the form of cash bonuses and, in years other than 2024, the granting of long-term incentive awards.

B. Oversight of Executive Compensation

Role of the Compensation Committee

Pursuant to the terms of its charter, the Compensation Committee is responsible for the review of all aspects of our executive compensation program and makes decisions regarding the compensation of the Named Executive Officer. Our Named Executive Officer for the year ended December 31, 2025 was Steven Shallcross, our Chief Executive Officer who also serves as our Chief Financial Officer.

The Compensation Committee's responsibilities include but are not limited to the following:

- Establishing on an annual basis the performance goals and objectives for purposes of determining the compensation of our Chief Executive Officer and other senior executive officers.
- Evaluating the Chief Executive Officer's and other senior executive officers' performance at least annually in light of those goals and objectives, and based upon these evaluations setting the compensation level for those officers.
- Reviewing the competitive position of, and making recommendations to, the Board of Directors with respect to the cash-based and equity-based compensation plans and our programs relating to compensation and benefits.
- Overseeing the administration of our stock option plan and incentive compensation plans, making recommendations to the Board of Directors regarding the granting of options and incentives and otherwise assisting the Board of Directors in administering awards under these plans.
- Reviewing the financial performance and operations of our major benefit plans.

Additional information regarding the Compensation Committee's responsibilities is set forth in its charter, which is posted on our website at *www.therivabio.com*. Information contained on our website is intended for informational purposes only and is not incorporated by reference into this Annual Report, and it should not be considered to be part of this Annual Report.

Role of the Chief Executive Officer

Our Chief Executive Officer makes recommendations to the Compensation Committee regarding the compensation of any other Named Executive Officers. The Chief Executive Officer does not participate in any discussions or processes concerning his own compensation and participates in a non-voting capacity in discussions or processes concerning the compensation of our other members of management. In addition to our Chief Executive Officer, other members of our management and consultants also attend Compensation Committee meetings from time to time and may take part in discussions of executive compensation.

C. Program Design

The Compensation Committee uses a simple and straightforward approach in compensating our Named Executive Officer in which base salary, annual incentives and stock options are the principal components. In addition, executive officers generally participate in the same benefit programs as other full-time employees.

Our executive compensation program is designed to provide executives with a reasonable level of fixed compensation through base salary and benefits, and an opportunity to earn incentive compensation through the annual and long-term incentive programs based on a mix of individual and corporate performance, individual performance and the value of our stock. We do not currently have formal policies for allocating compensation among base salary, performance-based bonus and equity awards. Instead our Compensation Committee uses its judgment to establish a total direct compensation opportunity for each Named Executive Officer that is a mix of current, short-term and long-term incentive compensation and cash and non-cash compensation that it believes appropriate to achieve the goals of our executive compensation program and corporate objectives. Our target pay mix places a significant emphasis on performance based variable compensation. The incentive plans are designed to pay well when performance meets or exceeds expectations and pay little or no incentive if performance is below expectations.

In designing and implementing our executive compensation program, our Compensation Committee considers our company's operating and financial objectives, including our risk profile, and the effect that its executive compensation decisions will have on encouraging our executive officers to take an appropriate level of business risk consistent with our overall goal of enhancing long-term stockholder value. In particular, the Compensation Committee considers those business risks identified in our risk factors and the known trends and uncertainties identified in our management discussion and analysis and considers how our executive compensation program serves to achieve our operating and financial objectives while at the same time mitigating any incentives for our executive officers to engage in excessive risk-taking to achieve short-term results that may not be sustainable in the long-term.

Target compensation comprises base salary and performance based variable compensation, including targeted cash bonus amounts and equity-based compensation. As an executive's level of responsibility increases, the Compensation Committee generally targets a greater portion of the executive's compensation to be contingent upon performance in the form of variable compensation. For example, historically our named executive officers have a higher percentage of compensation at risk (and thus greater upside and downside potential) relative to our other employees. The Compensation Committee believes this is appropriate because our named executive officers have the greatest influence on our performance.

During 2025, the salary for our Chief Executive Officer who also serves as our Chief Financial Officer was 67% of his target compensation package and performance based variable compensation comprised 33% of his target compensation. The increase in the percentage of non-variable compensation was due to the fact that no cash bonus was granted in 2025. Of the performance based variable compensation for the year ended December 31, 2025, all was equity-based compensation and none of the variable compensation was paid as a target cash bonus.

D. Compensation Review Process

The Compensation Committee annually reviews compensation for our Named Executive Officers. The Compensation Committee considers the executive's role and responsibilities, corporate and individual performance, and industry-wide compensation practices and trends for other companies of similar size. This approach is used to set base salaries, bonuses, stock option award levels and the mix of compensation elements.

We strive to attract and retain the most highly qualified executive officers in an extremely competitive market. Our Compensation Committee believes that it is important when making its compensation decisions to be informed as to the competitive market for executive talent, including the current practices of comparable public companies with which we compete for such talent. Consequently, in December 2023 our Compensation Committee reviewed an executive compensation report prepared by Meridian Compensation Partners, LLC ("Meridian") at the Compensation Committee's request. With respect to its analysis of the compensation of the Chief Executive Officer, the Compensation Committee took into account that our Chief Executive Officer also serves as our Chief Financial Officer, which is not typical for most companies.

While the Compensation Committee does take into consideration the data it reviewed, the Committee does not attempt to benchmark our executive compensation against any specific level, range, or percentile of compensation paid at any other companies, does not apply any specific measures of internal or external pay equity in reaching its conclusions, and does not employ tally sheets, wealth accumulation, or similar tools in its analysis. Rather, the Compensation Committee reviews compensation data from the report mentioned above as reference points in making executive compensation decisions especially in light of the fact that our Chief Executive Officer is also performing the role of Chief Financial Officer. The Compensation Committee's general aim is for our compensation to remain competitive with the market, falling above or below the median of the market data as appropriate based on corporate and individual executive performance, and other factors deemed to be appropriate. Competitive market positioning is only one of several factors, as described below, that the Compensation Committee considers in making compensation decisions, and therefore individual Named Executive Officer compensation may fall at varying levels as compared to the market data.

Our Compensation Committee values the opinion of our stockholders. At our 2025 Annual Meeting of Stockholders approximately 79% of the shares voted (excluding broker non-votes) were cast in support of our fiscal 2024 executive compensation and related disclosures. At that time, our Compensation Committee viewed those voting results as broad stockholder support for our executive compensation program and consequently made no material changes to the program or to our compensation policies. Our Compensation Committee will continue to consider input from stockholders, including through advisory votes on executive compensation, in making compensation decisions and reviewing executive compensation programs and policies.

We currently hold our advisory vote to approve the compensation of our named executive officers ("Say-on-Pay vote") every three years. Stockholders have an opportunity to cast an advisory vote on the frequency of the Say-on-Pay vote at least every six years, and the next advisory vote on the frequency of the Say-on-Pay vote will be at our 2028 Annual Meeting of Stockholders.

E. Components of Compensation

We provide four compensation components to Named Executive Officers:

- base salary;
- bonuses based on the achievement of specified goals and objectives;
- long-term incentives; and
- benefits

1. Base Salaries

We provide our Named Executive Officers a base salary commensurate with their position, responsibilities and experience. In setting the base salary, the Compensation Committee considers the scope and accountability associated with each Named Executive Officer's position and such factors as performance and experience of each Named Executive Officer. We design base pay to provide the essential reward for an employee's work that is required to be competitive in attracting talent. Once base pay levels are initially determined, increases in base pay may be provided to recognize an employee's specific performance achievements or expansion of responsibilities. The base salaries are targeted to be competitive with other similar biotechnology companies. Base salaries for the Named Executive Officers are set by their respective employment contracts and are reviewed annually by the Compensation Committee referencing an executive compensation report. The Compensation Committee engaged Meridian to provide such a report in 2023, and Mr. Shallcross' compensation for 2025 was determined by the Compensation Committee taking into account the findings and recommendations of this report. Mr. Shallcross' base salary was increased to $644,963 for the year ended December 31, 2024. Mr. Shallcross received a 3.5% merit increase to $667,536 for the year ended December 31, 2025, and on a 3.0 % merit increase to $687,562 for the 2026 fiscal year.

2. Bonuses

The Compensation Committee believes that the granting of a bonus is appropriate to motivate our Named Executive Officers. The bonuses are to be rewarded in the discretion of the Compensation Committee and the Board of Directors, based on a review of achievements for the year. The Compensation Committee focuses on individual performance, which enables the Compensation Committee to differentiate among executives and emphasize the link between personal performance and compensation. The Compensation Committee also used information from the executive compensation report prepared by Meridian in December 2023 in determining bonus amounts. Although the Compensation Committee does not use any fixed formula in determining bonuses, it does link bonuses to objectives the Compensation Committee deems important such as effective M&A strategy and implementation, financings, and achievement of clinical milestones.

- Mr. Shallcross' employment agreement provides that he is eligible for a target bonus of up to fifty percent (50%) of his base salary in cash. After considering Mr. Shallcross' achievement relative to performance goals in 2024, market conditions, the Company's cash position and stock price, the Compensation Committee approved a $200,000 cash bonus, or 62% of target. For the year ended December 31, 2025 in an effort to preserve cash the Compensation Committee did not approve a cash bonus for Mr. Shallcross but did approve an equity grant.

3. Long-Term Incentives

The Compensation Committee believes that a substantial portion of our Named Executive Officer's compensation should be awarded in equity-based compensation since equity-based compensation is directly linked to the interests of stockholders. The Compensation Committee has elected to grant stock options to the Named Executive Officers and other key employees as the primary long-term incentive vehicle. In making this determination, the Compensation Committee considered a number of factors including: the accounting impact, potential value of stock option grants versus other equity instruments and cash incentives, and the alignment of equity participants with stockholders. The Compensation Committee determined to grant stock options to:

- enhance the link between the creation of stockholder value and executive compensation;

- provide an opportunity for equity ownership;
- act as a retention tool; and
- provide competitive levels of total compensation.

In 2025, the Compensation Committee approved grants of options exercisable for 190,000 shares of Company Common Stock to Mr. Shallcross. The options had a grant date of April 28, 2025, an exercise price of $1.41, vest pro rata on a monthly basis over 36 months and expire seven years from date of grant. No options were granted to Mr. Shallcross in 2024.

On January 5, 2026, the Compensation Committee approved grants of options exercisable for 475,000 shares of Company Common Stock to Mr. Shallcross. The options had a grant date of January 5, 2026, an exercise price of $0.241 per share, vest pro rata on a monthly basis over 36 months and expire seven years from date of grant.

The Compensation Committee reviews the performance, potential burn rates and dilution levels to create an option pool that may be awarded to employee participants. Grants to the Named Executive Officers are determined by the Compensation Committee after reviewing market data, including the reports and analysis discussed above and after considering each executive's performance, role and responsibilities.

The Compensation Committee does not seek to time equity grants to take advantage of information, either positive or negative, about our company that has not been publicly disclosed. Option grants are effective on the date the award determination is made by the Compensation Committee and the exercise price of options is the closing market price of our Common Stock on the business day of the grant or, if the grant is made on a weekend or holiday, on the prior trading day.

4. Benefits

Named Executive Officers are eligible to participate in our standard medical, dental, vision, disability insurance, life insurance plans and other health and welfare plans provided to other full-time employees.

Each of our Named Executive Officers are entitled to participate in our 401(k) contributory defined contribution plan.

Pension Benefits

We do not currently provide pension arrangements or post-retirement health coverage for our employees, although we may consider such benefits in the future.

Retirement Benefits

Each of our Named Executive Officers is eligible to participate in our 401(k) contributory defined contribution plan. Pursuant to our 401(k) plan, all eligible employees, including our Named Executive Officers, are provided with a means of saving for their retirement. We currently match all participating employee contributions up to maximum of 4 percent of compensation which vest immediately.

Nonqualified Deferred Compensation

We do not provide any nonqualified deferred compensation plans to our employees, although we may consider such benefits in the future.

Risk Analysis of Our Compensation Program

Our Compensation Committee has reviewed our compensation policies as generally applicable to our employees and believes that our policies do not encourage excessive or inappropriate risk taking and that the level of risk that they do encourage is not reasonably likely to have a material adverse effect on us. As part of its assessment, the Compensation Committee considered, among other factors, the allocation of compensation among base salary and short- and long-term compensation, and our approach to establishing company-wide and individual financial, operational and other performance goals.

Outstanding Equity Awards at Fiscal Year End

The table below reflects all outstanding equity awards made to each of the Named Executive Officers that are outstanding at December 31, 2025. We currently grant stock-based awards pursuant to our 2020 Stock Incentive Plan (the "2020 Stock Plan") and have outstanding awards to Mr. Shallcross that were previously granted under our 2010 Stock Incentive Plan (the "2010 Stock Plan").

Name	Grant Date[1]	Number of Securities Underlying Unexercised Options Exercisable	Number of Securities Underlying Unexercised Options Unexercisable	Option Exercise Price ($)	Option Expiration Date
Steven Shallcross	04/29/2025	36,944	153,056	$ 1.41	04/29/2032
	12/14/2023	18,667	9,334	$ 14.75	12/14/2030
	12/15/2022	19,001	—	14.50	12/15/2029
	12/23/2021	2,601	—	$ 82.75	12/23/2028
	12/30/2020	1,801	—	$ 104.25	12/30/2027
	12/04/2019	1,801	—	$ 104.50	12/04/2026

(1) Options vested or will vest pro rata, on a monthly basis, over 36 months beginning on their respective grant dates.

Employment Agreements

Steven A. Shallcross, Chief Executive Officer, Chief Financial Officer

On January 3, 2022, we entered into a three-year employment agreement with Mr. Shallcross (the "2022 Shallcross Employment Agreement") to serve as our Chief Executive Officer and to continue to serve as our Chief Financial Officer. The 2022 Shallcross Employment Agreement replaced the prior employment agreement with us that Mr. Shallcross entered into on December 6, 2018, as amended December 5, 2019. Mr. Shallcross has served as our Chief Financial Officer since June 1, 2015, initially pursuant to the terms of a two year employment agreement that we entered with him on April 28, 2015 (the "Initial Shallcross Employment Agreement") and then pursuant to an employment agreement we entered into with him on December 6, 2018, which replaced the Initial Shallcross Agreement (the "Amended Shallcross Employment Agreement"). Mr. Shallcross does not receive additional compensation for service as our director. The 2022 Shallcross Employment Agreement expired on January 3, 2025. Pursuant to the 2022 Shallcross Employment Agreement, Mr. Shallcross was initially entitled to an annual base salary of $585,000 which was increased to $614,250 for the year ended December 31, 2023, increased on December 14, 2023 to $644,963 to reflect a 5% merit increase and further increased on December 13, 2024 to $667,526 to reflect a 3.5% merit increase. Mr. Shallcross was also eligible to receive an annual cash performance bonus targeted at fifty percent (50%) of his annual base salary and payable based upon the assessment of the Board of Mr. Shallcross's performance, as well as discretionary annual equity awards pursuant to the Company's incentive plans. On March 3, 2025, we entered into a new employment agreement with Mr. Shallcross (the "2025 Shallcross Employment Agreement") for a term of two years, pursuant to which he continues to serve as our Chief Executive Officer and Chief Financial Officer and continues to receive the same compensation that he received pursuant to the 2022 Shallcross Employment Agreement. The material terms of each of the 2022 Shallcross Employment Agreement and the 2025 Shallcross Employment Agreement, (collectively, the "Shallcross Employment Agreements") are substantially the same, other than the term of the agreements, and are set forth below.

The Shallcross Employment Agreements each contain confidentiality obligations and invention assignments by Mr. Shallcross and non-solicitation and non-competition provisions.

The Shallcross Employment Agreements provide that if Mr. Shallcross's employment is terminated for any reason, he or his estate as the case may be, will be entitled to receive the unpaid base salary through the date of termination and accrued vacation, any unpaid annual bonus earned with respect to any calendar year ending on or preceding the date of termination, expense reimbursement and any other entitlements accrued by him to the extent not previously paid (the "Accrued Obligations"); provided, however, that if his employment is terminated (i) by us without Cause or by Mr. Shallcross for Good Reason (as each is defined in the Shallcross Employment Agreements) then, subject to him executing a general release in form acceptable to us that becomes effective, in addition to paying the Accrued Obligations, (a) we will continue to pay his then current base salary and if the Executive timely elects continued coverage under COBRA, we will continue to provide benefits at least equal to those that were provided at the time of termination for a period of twelve (12) months and (b) all unvested equity awards will vest and he shall have the right to exercise any such vested equity awards until the earlier of eighteen (18) months after termination or the remaining term of the awards; or (ii) by reason of his death or Disability (as defined in the Shallcross Employment Agreements), then in addition to paying the Accrued Obligations, Mr. Shallcross or his estate would have the right to exercise any vested options until the earlier of six (6) months after termination or the remaining term of the awards. In such event, if Mr. Shallcross commenced employment with another employer and becomes eligible to receive medical or other welfare benefits under another employer-provided plan, the medical and other welfare benefits to be provided by us as described herein would terminate.

The Shallcross Employment Agreements each provide that upon the closing of a "Change in Control" (as defined in the Shallcross Employment Agreements), all unvested options shall immediately vest and the time period that Mr. Shallcross will have to exercise all vested stock options and other awards that Mr. Shallcross may have will be equal to the shorter of: (i) eighteen (18) months after termination, or (ii) the remaining term of the award(s). If within one (1) year after the occurrence of a Change in Control, Mr. Shallcross terminates his employment for "Good Reason" or we terminate Mr. Shallcross's employment for any reason other than death, disability or Cause, Mr. Shallcross will be entitled to receive: (i) the portion of his base salary for periods prior to the effective date of termination accrued but unpaid (if any); (ii) all unreimbursed expenses (if any); (iii) an aggregate amount (the "Change in Control Severance Amount") equal to two (2) times the sum of his base salary plus an amount equal to the bonus that would be payable if the "target" level performance were achieved under the Company's annual bonus plan (if any) in respect of the fiscal year during which the termination occurs (or the prior fiscal year if bonus levels have not yet been established for the year of termination) subject to him executing a general release in form acceptable to us that becomes effective. If within two (2) years after the occurrence of a Change in Control, Mr. Shallcross terminates his employment for "Good Reason" or the Company terminates Mr. Shallcross's employment for any reason other than death, disability or Cause, Mr. Shallcross will be entitled to also receive for the period of two (2) consecutive years commencing on the date of such termination of his employment, medical, dental, life and disability insurance coverage for him and the members of his family that are not less favorable to him than the group medical, dental, life and disability insurance coverage carried by the Company for him subject to him executing a general release in form acceptable to the Company that becomes effective. The Change in Control Severance Amount is to be paid in a lump sum if the Change in Control event constitutes a "change in the ownership" or a "change in the effective control" of the Company or a "change in the ownership of a substantial portion of a corporation's assets" (each within the meaning of Section 409A of the Internal Revenue Code ("Rule 409A")), or in 48 substantially equal payments, if the Change in Control event does not so comply with Section 409A.

Clawback Policy

The Board has adopted a clawback policy which allows us to recover performance-based compensation, whether cash or equity, from a current or former executive officer in the event of an Accounting Restatement. The clawback policy defines an Accounting Restatement as an accounting restatement of our financial statements due to our material noncompliance with any financial reporting requirement under the securities laws. Under such policy, we may recoup incentive-based compensation previously received by an executive officer that exceeds the amount of incentive-based compensation that otherwise would have been received had it been determined based on the restated amounts in the Accounting Restatement.

The Board has the sole discretion to determine the form and timing of the recovery, which may include repayment, forfeiture and/or an adjustment to future performance-based compensation payouts or awards. The remedies under the clawback policy are in addition to, and not in lieu of, any legal and equitable claims available to the Company. The clawback policy is incorporated by reference in this Annual Report as an exhibit.

Company Policies and Practices Related to the Grant of Certain Equity Awards Close in Time to the Release of Material Nonpublic Information

We do not have a formal written policy in place with regard to the timing of awards of options in relation to the disclosure by us of material nonpublic information, the Compensation Committee does not seek to time equity grants to take advantage of information, either positive or negative, about our company that has not been publicly disclosed. We intend to issue equity grants to our officers and/or directors, if granted, at the same time each year, typically in connection with our last meeting of the Board of Directors each fiscal year. Option grants are effective on the date the award determination is made by the Compensation Committee, and the exercise price of options is the closing market price of our Common Stock on the business day of the grant or, if the grant is made on a weekend or holiday, on the prior business day. During the fiscal year ended December 31, 2024, our Named Executive Officer was not awarded any stock options due to the lack of availability of awards.

In 2025, the Compensation Committee approved grants of options exercisable for 190,000 shares of Company Common Stock to Mr. Shallcross. During 2025, we did not grant stock options (or similar awards) to our Named Executive Officers during the period beginning four business days before and ending one business day after the filing of any Company periodic report on Form 10-Q or Form 10-K, or the filing or furnishing of any Company Form 8-K that disclosed any material non-public information.

We did not time the disclosure of material nonpublic information for the purpose of affecting the value of executive compensation.

Compensation of Directors

The following table sets forth information for the fiscal year ended December 31, 2025 regarding the compensation of our directors who at December 31, 2025 were not also our Named Executive Officer.

Name	Fees Earned or Paid in Cash	Option Awards[1]	Other Compensation	Total
Jeffrey J. Kraws	$ 180,250	$ 26,571	$ —	$ 206,821
John Monahan	$ 77,750	$ 26,571	$ —	$ 104,321
Jeffrey Wolf	$ 70,750	$ 26,571	$ —	$ 97,321

(1) As of December 31, 2025, the following are the outstanding aggregate number of option awards held by each of our directors who were not also our Named Executive Officer:

Name	Option Awards (#)
Jeffrey J. Kraws	35,800
John Monahan	34,900
Jeffrey Wolf	35,800

Our board members were compensated based on the following policies during 2025:

- Our independent, non-executive Chairman of the Board of Directors received an annual cash retainer of $154,000.
- Other non-employee members of the Board of Directors were entitled to an annual cash retainer of $47,000.
- Non-employee directors were entitled to annual cash fees of $7,500, $5,000 and $3,750 for service as a member of the Audit, Compensation and Nominations Committees, respectively.

- Non-employee directors were entitled to an additional annual cash fee of $15,000, $10,000 and $7,500 for service as Chairman of the Audit, Compensation and Nominations Committees.

- Non-employee directors were granted options to purchase 25,000 shares of Common Stock, which vest pro rata on a monthly basis over 12 months from the date of grant.

In setting 2025 compensation for directors, the Compensation Committee relied on a report prepared by Meridian in December 2023.

Compensation Committee Interlocks

During the last fiscal year ended December 31, 2025, none of our executive officers served on the Board of Directors or Compensation Committee of any other entity whose officers served either on our Board of Directors or Compensation Committee.

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

The following table sets forth information, as of March 12, 2026, or as otherwise set forth below, with respect to the beneficial ownership of our common stock (i) all persons known to us to be the beneficial owners of more than 5% of the outstanding shares of our common stock; (ii) each of our directors and our named executive officers named in the Summary Compensation Table; and (iii) all of our directors and our current executive officer as a group.

	Shares Owned [2]	
Name and Address of Beneficial Ownership [1]	Number of Shares Owned	Percentages of Shares [3]
Named Executive Officers and Directors		
Jeffrey J. Kraws [4]	54,576	*
Steven Shallcross [5]	188,603	*
Jeffrey Wolf [6]	54,550	*
John Monahan [7]	53,650	*
All current officers and directors as a group (4 persons)	351,379	*

* represents less than 1% of our Common Stock

(1) The address for each officer and directors is 9605 Medical Center, Suite 270, Rockville, Maryland 20850.

(2) Beneficial ownership is determined in accordance with SEC rules and generally includes voting or investment power with respect to securities. Except as indicated in the footnotes to the table, to the knowledge of the Company, the persons named in the table have sole voting and investment power with respect to all shares of Common Stock, preferred stock, options and/or warrants shown as beneficially owned by them, subject to community property laws, where applicable. Pursuant to the rules of the SEC, the number of shares of our Common Stock deemed outstanding includes shares issuable pursuant to options held by the respective person or group that are currently exercisable or may be exercised within 60 days of March 12, 2026.

(3) As of March 10, 2026, the Company had 45,892,668 shares of Common Stock outstanding.

(4) Includes 54,550 shares issuable upon exercise of options held by Mr. Kraws that are exercisable within the 60-day period following March 12, 2026.

(5) Includes 149,889 shares issuable upon exercise of options held by Mr. Shallcross and 28,704 shares of common stock issuable upon exercise of options held by Mrs. Shallcross (Mr. Shallcross's wife) that are exercisable within the 60-day period following March 12, 2026.

(6) Includes 54,550 shares issuable upon exercise of options held by Mr. Wolf that are exercisable within the 60-day period following March 12, 2026.

(7) Includes 53,650 shares issuable upon exercise of options held by Dr. Monahan that are exercisable within the 60-day period following March 12, 2026.

Equity Compensation Plan Information

The following table sets forth information about the securities authorized for issuance under our equity compensation plans for the fiscal year ended December 31, 2025.

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
Equity compensation plans approved by stockholders:			
2010 Stock Incentive Plan	5,893	$ 107.08	—
2020 Stock Incentive Plan	1,108,535	4.29	3,391,465
Equity compensation plans not approved by stockholders	N/A	N/A	N/A
Total	1,114,428	$ 4.84	3,391,465

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

Pursuant to our Audit Committee charter, our Audit Committee shall review on an on-going basis for potential conflicts of interest, and approve if appropriate, all our "Related Party Transactions" as required by Section 120 of the NYSE American Company Guide. For purposes of the Audit Committee Charter, "Related Party Transactions" shall mean those transactions required to be disclosed pursuant to SEC Regulation S-K, Item 404.

Except as disclosed under "Executive Compensation," and below there were no related party transactions during the two years ended December 31, 2025 or the current year.

On December 15, 2022, we approved the retention of MaryAnn Shallcross, the wife of Steven Shallcross, as director of Clinical Operations, for compensation of $145,000 and the grant of an option to purchase 2,000 shares of Common Stock having a value of $20,000. Ms. Shallcross had been performing services for us during 2022 for total compensation of less than $120,000. On December 14, 2023, the Company approved the retention of MaryAnn Shallcross, the wife of Steven Shallcross, as Director of Clinical Operations, for compensation of $152,000, a bonus of $70,000 and the grant of an option to purchase 3,000 shares of Common Stock having a value of $30,000. During the year ended December 31, 2023, the Company had $145,000 in compensation expense related to Mrs. Shallcross. On December 13, 2024, the Company approved the compensation of MaryAnn Shallcross of $157,000, a bonus of $45,000 and on April 29, 2029, the Company approved grant of an option to purchase 25,000 shares of Common Stock having a value of $27,000. During the year ended December 31, 2025, the Company had $202,000 in compensation expense, related to Ms. Shallcross. Ms. Shallcross was one of the seven employees whose employment was terminated in connection with the Company's workforce reduction announced on September 30, 2025. We entered into a Separation Letter Agreement with Ms. Shallcross pursuant to which she received payment of her base salary for three months until December 31, 2025, acceleration of all unvested outstanding equity awards that had been granted to her, and an extension of the exercise period of all of her outstanding options until December 31, 2026.

Director Independence

Our Common Stock is listed on the NYSE American. Under the rules of NYSE American, independent directors must comprise a majority of a listed company's board of directors and all members of our audit, compensation and nominations committees must be independent. Audit committee members must also satisfy the independence criteria set forth in Rule 10A-3 under the Exchange Act. Under the rules of the NYSE American, a director will only qualify as an "independent director" if, in the opinion of that company's

board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

In order to be considered to be independent for purposes of Rule 10A-3, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors, or any other board committee: (1) accept, directly or indirectly, any consulting, advisory or other compensatory fee from the listed company or any of its subsidiaries or (2) be an affiliated person of the listed company or any of its subsidiaries.

The Board of Directors undertook a review of the independence of the members of the Board of Directors and considered whether any director has a material relationship with our company that could compromise his or her ability to exercise independent judgment in carrying out his or her responsibilities. Based upon information requested from and provided by each director concerning their background, employment and affiliations, including family relationships, the Board of Directors has determined that Mr. Kraws, Dr. Monahan and Mr. Wolf, representing a majority of the members of our Board of Directors, are "independent" as that term is defined under the rules of NYSE American. See Part III–Item 10 under the heading "Directors, Executive Officers and Corporate Governance" of this Annual Report for additional information related to director independence.

Item 14. ***Principal Accountant Fees and Services.***

Independent Registered Public Accounting Firm Fees and Services

The following table sets forth the aggregate fees including expenses billed to us for the years ended December 31, 2025 and 2024 by BDO USA, P.C.

	December 31,	
	2025	2024
Audit Fees	$ 652,000	$ 659,249
Tax Fees	—	—
Total Fees (1)	$ 652,000	$ 659,249

(1) Audit fees and expenses were for professional services rendered for the audit and reviews of the consolidated financial statements of the Company, professional services rendered for issuance of consents and assistance with review of documents filed with the SEC.

Audit Committee Pre-Approval Policy

The Audit Committee has adopted procedures for pre-approving all audit and non-audit services provided by the independent registered public accounting firm, including the fees and terms of such services. These procedures include reviewing detailed back-up documentation for audit and permitted non-audit services. The documentation includes a description of, and a budgeted amount for, particular categories of non-audit services that are recurring in nature and therefore anticipated at the time that the budget is submitted. Audit Committee approval is required to exceed the pre-approved amount for a particular category of non-audit services and to engage the independent registered public accounting firm for any non-audit services not included in those pre-approved amounts. For both types of pre-approval, the Audit Committee considers whether such services are consistent with the rules on auditor independence promulgated by the SEC and the Public Company Accounting Oversight Board (PCAOB). The Audit Committee also considers whether the independent registered public accounting firm is best positioned to provide the most effective and efficient service, based on such reasons as the auditor's familiarity with our business, people, culture, accounting systems, risk profile, and whether the services enhance our ability to manage or control risks and improve audit quality. The Audit Committee may form and delegate pre-approval authority to subcommittees consisting of one or more members of the Audit Committee, and such subcommittees must report any pre-approval decisions to the Audit Committee at its next scheduled meeting. All of the services provided by the independent registered public accounting firm were pre-approved by the Audit Committee.

PART IV

Item 15. ***Exhibits and Financial Statement Schedules.***

(a)(1) The following financial statements are included in this Annual Report on Form 10-K for the fiscal years ended December 31, 2025 and 2024.

1. Independent Registered Public Accounting Firm
2. Consolidated Balance Sheets as of December 31, 2025 and 2024
3. Consolidated Statements of Operations for the years ended December 31, 2025 and 2024
4. Consolidated Statements of (Deficit) Equity for the years ended December 31, 2025 and 2024
5. Consolidated Statements of Cash Flows for the years ended December 31, 2025 and 2024
6. Notes to Consolidated Financial Statements

(a)(2) All financial statement schedules have been omitted as the required information is either inapplicable or included in the Consolidated Financial Statements or related notes.

(a)(3) Exhibits

EXHIBIT INDEX

The following exhibits are either filed as part of this report or are incorporated herein by reference:

1.1	Amended and Restated At Market Issuance Sales Agreement by and among Theriva Biologics, Inc., B. Riley Securities, Inc. and A.G.P./Alliance Global Partners, dated February 9, 2021 (Incorporated by reference to Exhibit 1.1 of the Registrant's Current Report on Form 8-K filed February 10, 2021), File No. 001-12584.)
1.2	Amendment No. 1, dated May 3, 2021, to the Amended and Restated At Market Issuance Sales Agreement by and among Theriva Biologics, Inc., B. Riley Securities, Inc. and A.G.P./Alliance Global Partners, dated February 9, 2021 ((Incorporated by reference to Exhibit 1.2 of the Registrant's Current Report on Form 8-K filed May 3, 2021)
1.3	Amendment No. 2, dated May 2, 2024, to the Amended and Restated At Market Issuance Sales Agreement by and among Theriva Biologics, Inc., and A.G.P./Alliance Global Partners, dated February 9, 2021 (Incorporated by reference to Exhibit 10.3 of the Registrant's Current Report on Form 8-K filed May 2, 2024)
1.4	Placement Agency Agreement, dated as of September 26, 2024, by and between Theriva Biologics, Inc. and A.G.P./Alliance Global Partners, as placement agent (Incorporated by reference to Exhibit 1.1 of the Registrant's Current Report on Form 8-K Filed September 30, 2024, File No. 001-12584)
1.5	Placement Agency Agreement, dated as of May 7, 2025, by and between Theriva Biologics, Inc. and A.G.P./Alliance Global Partners, as placement agent (Incorporated by reference to Exhibit 1.1 of the Registrant's Current Report on Form 8-K filed May 8, 2025, File No. 001-12584)
2.1	Share Purchase Agreement by and among Theriva Biologics, Inc., VCN Biosciences, S.L. and the shareholders of VCN Biosciences, S.L. dated December 14, 2021(Incorporated by reference to Exhibit 2.1 of the Registrant's Current Report on Form 8-K filed December 14, 2021, File No. 001-12584.)
2.2	Amendment, dated March 9, 2022, to the Share Purchase Agreement, by and among Theriva Biologics, Inc., VCN Biosciences, S.L. and the shareholders of VCN Biosciences, S.L., dated December 14, 2021 (Incorporated by reference to Exhibit 2.2 of the Registrant's Current Report on Form 8-K filed March 11, 2022, File No. 001-12584.)
3.1	Certificate of Incorporation, as amended (Incorporated by reference to (i) Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed October 16, 2008, File No. 001-12584, (ii) Exhibit 3.1 of the Registrant's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2001 filed August 14, 2001, File No. 001-12584; and (iii) Exhibits 3.1, 4.1 and 4.2 of the Registrant's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 1998 filed August 14, 1998, File No. 001-12584.)
3.2	Articles of Merger (Incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed October 19, 2009, File No. 001-12584.)
3.3	Certificate of Merger filed with the Secretary of State of Delaware (Incorporated by reference to Exhibit 3.2 of the Registrant's Current Report on Form 8-K filed October 19, 2009, File No. 001-12584.)
3.4	Articles of Incorporation filed with the Nevada Secretary of State (Incorporated by reference to Exhibit 3.3 of the Registrant's Current Report on Form 8-K filed October 19, 2009, File No. 001-12584.)
3.5	Certificate of Amendment to Articles of Incorporation (Incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed February 16, 2012, File No. 001-12584.)
3.6	Certificate of Amendment to Certificate of Incorporation. (Incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed May 18, 2015, File No. 001-12584.)

3.7	Certificate of Amendment to Certificate of Incorporation. (Incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed September 8, 2017, File No. 001-12584.)
3.8	Certificate of Designations for Series A Preferred Stock to Certificate of Incorporation (Incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed September 12, 2017, File No. 001-12584.)
3.9	Certificate of Change Pursuant to NRS 78. 209 (Incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed August 13, 2018, File No. 001-12584.)
3.10	Certificate of Amendment to Articles of Incorporation (Incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed September 26, 2018, File No. 001-12584.)
3.11	Certificate of Designations for Series B Preferred Stock to Certificate of Incorporation (Incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed October 15, 2018, File No. 001-12584.)
3.12	Certificate of Amendment to Certificate of Designations for Series B Preferred Stock to Certificate of Incorporation (Incorporated by reference to Exhibit 3.2 of the Registrant's Current Report on Form 8-K filed October 15, 2018, File No. 001-12584.)
3.13	Certificate of Amendment to the Certificate of Designation for the Series A Convertible Preferred Stock (Incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K/A filed on February 1, 2021 File No. 001-12584.)
3.14	Certificate of Change filed with the Secretary of State of the State of Nevada on July 21, 2022 (effective as of July 25, 2022) (Incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed on July 25, 2022 (File No. 001-12584.)
3.15	Form of Certificate of Designation of Series C Convertible Preferred Stock (Incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed on July 29, 2022 (File No. 001-12584.)
3.16	Form of Certificate of Designation of Series D Convertible Preferred Stock (Incorporated by reference to Exhibit 3.2 of the Registrant's Current Report on Form 8-K filed on July 29, 2022 (File No. 001-12584.)
3.17	Certificate of Amendment to Articles of Incorporation (Incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed on October 12, 2022 (File No. 001-12584.)
3.18	Certificate of Change to Articles of Incorporation (Incorporated by reference to Exhibit 3.2 of the Registrant's Current Report on Form 8-K filed on October 12, 2022 (File No. 001-12584.)
3.19	Second Amended and Restated Bylaws (Incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed August 11, 2023, File No. 001-12584.)
3.20	Certificate of Change filed with the Secretary of State of the State of Nevada on August 22, 2024 (effective as of August 26, 2024) (Incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed August 26, 2024, File No. 001-12584.)
3.21	Certificate of Change to the Articles of Incorporation (Incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed November 1, 2024, File No. 001-12584.)
4.1	Specimen Stock Certificate (Incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-3 filed on July 3, 2013, File No. 333-189794.)
4.2	Form of Common Warrant (Incorporated by reference to Exhibit 4.1 of the Registrant's Current Report on Form 8-K Filed September 30, 2024, File No. 001-12584)

4.3	Form of Pre-Funded Warrant (Incorporated by reference to Exhibit 4.2 of the Registrant's Current Report on Form 8-K Filed September 30, 2024, File No. 001-12584)
4.4	Form of Common Warrant (Incorporated by reference to Exhibit 4.1 of the Registrant's Current Report on Form 8-K filed May 8, 2025, File No. 001-12584)
4.5	Form of Pre-Funded Warrant (Incorporated by reference to Exhibit 4.2 of the Registrant's Current Report on Form 8-K filed May 8, 2025, File No. 001-12584)
4.6	Form of New Warrant (Incorporated by reference to Exhibit 4.1 of the Registrant's Current Report on Form 8-K filed October 17, 2025, File No. 001-12584)
4.7	Description of Securities of Theriva Biologics, Inc. (1)
10.1*	2007 Stock Incentive Plan (Incorporated by reference to Exhibit 4.2 of the Registrant's Registration Statement on Form S-8 filed January 18, 2008, File No. 333-148764.)
10.2*	Form of Director/Officer Indemnification Agreement (Incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed January 6, 2009, File No. 001-12584.)
10.3*	2010 Stock Incentive Plan (Incorporated by reference to Exhibit 4.1 of the Registrant's Registration Statement on Form S-8 filed November 29, 2010, File No. 333-170858.)
10.4	Asset Purchase Agreement dated November 8, 2012 between Theriva Biologics, Inc. and Prev ABR LLC (Incorporated by reference to Exhibit 10.4 of the Registrant's Annual Report on Form 10-K filed on March 16, 2022, File No. 001-12584)
10.5+	Patent License Agreement dated December 19, 2012 between Theriva Biologics, Inc. and The University of Texas at Austin (Incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed December 21, 2012, File No. 001-12584.)
10.6*	Amended and Restated 2010 Stock Incentive Plan (Incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-8 filed on November 15, 2013, File No. 333-192355.)
10.7*	Amended and Restated 2010 Stock Incentive Plan. (Incorporated by reference to Exhibit B to the Definitive Proxy Statement filed on April 13, 2015, File No. 001-12584.)
10.8	Lease dated April 14, 2015 between Registrant. and MCC3, LLC (Incorporated by reference to Exhibit 10.8 of the Registrant's Annual Report Form 10-K filed on March 25, 2024, File No. 001-12584)
10.9*	Theriva Biologics, Inc. 2010 Stock Incentive Plan, as amended and restated on May 15, 2015. (Incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-8 filed on August 10, 2015, File No. 333-206268.)
10.10*	Form of Stock Option Agreement. (Incorporated by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K filed December 10, 2015, File No. 001-12584.)
10.11*	Theriva Biologics, Inc. 2010 Stock Incentive Plan, as amended and restated on May 31, 2016. (Incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-8 filed on August 31, 2016, File No. 333-206268.)
10.12*	Amended and Restated 2010 Stock Incentive Plan (Incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-8 filed on September 8, 2017, File No. 333-220401.)
10.13*	Theriva Biologics, Inc. 2010 Stock Incentive Plan, as amended (incorporated by reference to Appendix A to the Definitive Proxy Statement filed with the Securities and Exchange Commission on July 15, 2019, File No. 001-12584)

10.14+	Clinical Trial Agreement between Washington University School of Medicine in St. Louis and Theriva Biologics, Inc. dated August 7, 2019 (Incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on August 8, 2019, File No. 001-12584)
10.15*	Theriva Biologics, Inc. 2020 Stock Incentive Plan (Incorporated by reference to Appendix A to the Registrant's Definitive Proxy Statement on Schedule 14A filed on August 4, 2020, File No. 001-12584)
10.16*	Form of Incentive Stock Option Grant Agreement (Incorporated by reference to Exhibit 4.11 to the Registration Statement on Form S-8 filed on October 28, 2020, File No. 333-249712)
10.17*	Form of Nonqualified Stock Option Grant Agreement (Incorporated by reference to Exhibit 4.12 to the Registration Statement on Form S-8 filed on October 28, 2020, File No. 333-249712)
10.18*	Form of Restricted Stock Unit Award Agreement (Incorporated by reference to Exhibit 4.13 to the Registration Statement on Form S-8 filed on October 28, 2020, File No. 333-249712)
10.19+	Second Amendment to Lease dated May 6, 2021 by and between Registrant and ARE-Maryland No. 50, LLC (Incorporated by reference to Exhibit 10.19 of the Registrant's Annual Report Form 10-K filed on March 25, 2024, File No. 001-12584)
10.20*	Employment Agreement with Steven Shallcross dated January 3, 2022 (Incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on January 4, 2022, File No. 001-12584)
10.21+	Contract to Grant Marketing License for Catalan Institute of Oncology Patent Ownership Application to VCN Biosciences S.L. (Incorporated by reference to Exhibit 10.32 of the Registrant's Annual Report on Form 10-K filed on March 16, 2022, File No. 001-12584)
10.22+	License Agreement between Bellvitge Biomedical Research Institute Foundation (Idibell) and VCN Biosciences S.L. dated May 4, 2016 (Incorporated by reference to Exhibit 10.33 of the Registrant's Annual Report on Form 10-K filed on March 16, 2022, File No. 001-12584)
10.23+	Technology Transfer Agreement between Bellvitge Biomedical Research Institute and VCN Biosciences S.L. dated August 31, 2010 (Incorporated by reference to Exhibit 10.34 of the Registrant's Annual Report on Form 10-K filed on March 16, 2022, File No. 001-12584)
10.24+	Collaboration Agreement to Conduct a Clinical Trial and Grant Operating License Agreement between Hospital Sant Joan Dee Deu and VCN Biosciences, S.L dated February 15, 2016 (Incorporated by reference to Exhibit 10.35 of the Registrant's Annual Report on Form 10-K filed on March 16, 2022, File No. 001-12584)
10.25*	Employment Agreement with Mary Ann Shallcross dated April 8, 2022 (Incorporated by reference to Exhibit 10.26 of the Registrant's Annual Report Form 10-K filed on March 25, 2024, File No. 001-12584)
10.26	Securities Purchase Agreement between Synthetic Biologics Inc. and MSD Credit Opportunity Master Fund, L.P., dated as of July 28, 2022 (Incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on July 29, 2022, File No. 001-12584)
10.27	Amendment No. 1 dated as of August 9, 2022 to Securities Purchase Agreement between Synthetic Biologics Inc. and MSD Credit Opportunity Master Fund, L.P., dated as of July 28, 2022 (Incorporated by reference to Exhibit 10.2 of the Registrant's Quarterly Report on Form 10-Q filed on August 11, 2022, File No. 001-12584)
10.28*	Amendment No. 1 to Employment Agreement between Theriva Biologics, Inc. and Steven A. Shallcross, dated as of December 15, 2022 (Incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on December 20, 2022, File No. 001-12584)

10.29*	Amendment No. 1 to Employment Agreement between Theriva Biologics, Inc. and Francis Tufaro, dated as of December 15, 2022 (Incorporated by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K filed on December 20, 2022, File No. 001-12584)
10.34	Form of Securities Purchase Agreement (Incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K Filed September 30, 2024, File No. 001-12584)
10.35	Amendment No. 2 to the Theriva Biologics, Inc. 2020 Stock Incentive Plan (Incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed November 1, 2024, File No. 001-12584)
10.36	Employment Agreement between Theriva Biologics, Inc. and Steven A. Shallcross, dated as of March 3, 2025(Incorporated by reference to Exhibit 10.36 of the Registrant's Annual Report on Form 10-K filed March 6, 2025, File No. 001-12584)
10.37	Form of Securities Purchase Agreement (Incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed May 8, 2025, File No. 001-12584)
10.38	Amendment No. 3 to the Theriva Biologics, Inc. 2020 Stock Incentive Plan (Incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed September 4, 2025, File No. 001-12584)
10.39	Form of Warrant Inducement Agreement (Incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed October 17, 2025, File No. 001-12584)
10.40+	License Agreement between Theriva Biologics, Inc. and Rasayana Therapeutics, Inc., dated as of February 17, 2026 (1)
19.1	Insider Trading Policy (Incorporated by reference to Exhibit 19.1 of the Registrant's Annual Report on Form 10-K filed March 6, 2025, File No. 001-12584)
21.1	List of Subsidiaries (Incorporated by reference to Exhibit 21.1 of the Registrant's Annual Report on Form 10-K Filed March 25, 2024, File No. 001-12584)
23.1	Consent of Independent Registered Public Accounting Firm (BDO USA, P.C.) (1)
31.1	Certification of Steven A. Shallcross, Chief Executive Officer and Chief Financial Officer, pursuant to Rule 13a-14(a)/15d-14(a) (1)
32.1	Certification of Steven A. Shallcross, Chief Executive Officer and Chief Financial Officer pursuant to Section 1350 of the Sarbanes-Oxley Act of 2002 (1)
97.1	Clawback Policy (Incorporated by reference to Exhibit 97.1 of the Registrant's Annual Report on Form 10-K Filed March 25, 2024, File No. 001-12584)

101.INS	Inline 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 [(1)]
101.SCH	Inline XBRL Taxonomy Extension Schema Document [(1)]
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document [(1)]
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document [(1)]
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document [(1)]
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document [(1)]
104	Cover Page Interactive Data File (formatted in XBRL in Exhibit 101)

(1) Filed herewith.

*** Management contract or compensatory plan or arrangement required to be identified pursuant to Item 15(a)(3) of this report.**

\+ The Company omitted certain portions of these agreements in accordance with Item 601 (b)(10) of Regulation S-K. The Company agrees to furnish unredacted copies of these exhibits to the SEC upon request.

Item 16. ***Form 10-K Summary.***

Not applicable.

SIGNATURES

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

THERIVA BIOLOGICS, INC.
By: /s/ Steven A. Shallcross
Steven A. Shallcross
Chief Executive Officer, Chief Financial Officer and Director
(Principal Executive Officer, Principal Financial Officer and Principal Accounting Officer)
Date: March 12, 2026

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Steven A. Shallcross, his true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments to this report, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent, 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 all that said attorneys-in-fact and agents, or his substitutes or substitute, may lawfully do or cause to be done by virtue hereof.

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

Date: March 12, 2026
By : /s/ Steven A. Shallcross
Steven A. Shallcross
Chief Executive Officer, Chief Financial Officer and Director
(Principal Executive Officer, Principal Financial Officer and Principal Accounting Officer)

Date: March 12, 2026
By : /s/ Jeffrey J. Kraws
Jeffrey J. Kraws
Chairman

Date: March 12, 2026
By: /s/ John J. Monahan
John J. Monahan
Director

Date: March 12, 2026
By: /s/ Jeffrey Wolf
Jeffrey Wolf
Director


Theriva
BIOLOGICS