Predictive Oncology Inc. (POAI) Rating: Buy

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PREDICTIVE Patient Drug Response at Preclinical Stage; Initiating With Buy and a \$3 PT

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Stock Data			8/16/2024
Price			\$0.88
Exchange			NASDAQ
Price Target			\$3.00
52-Week High			\$4.92
52-Week Low			\$0.85
Enterprise Valu	ıe (M)		\$(0)
Market Cap (M)		\$6
Shares Outstar	J ()		6.7
3 Month Avg V			4,301,513
Short Interest (•		0.22
Balance Sheet	t Metrics		
Cash (M)			\$6.6
Total Debt (M)			\$0.3
Total Cash/Sha			\$0.99
EPS (\$) Diluted			
Full Year - Dec	2023A	2024E	2025E
1Q	(0.86)	(1.04)A	(0.10)
2Q	(0.98)	(0.68)A	(0.09)
3Q	(0.78)	(0.32)	(0.10)
4Q	(0.86)	(0.26)	0.05
FY	(3.48)	(2.03)	(0.16)
Revenue (\$M)			
Full Year - Dec	2023A	2024E	2025E
1Q	0.2	0.4A	1.5
2Q	0.5	0.3A	1.5
3Q	0.7	0.5	1.5
4Q	0.3	0.4	5.0
FY	1.8	1.5	9.3



Addressing the challenge of patient heterogeneity in early drug development. Predictive Oncology is a biotech company utilizing artificial intelligence (AI) to support the development of cancer therapy. The company's proprietary AI platform—Patient-centric Drug Discovery using Active Learning (PEDAL)— enables prediction of tumor drug response among cancer patients at preclinical stages. By introducing the element of patient heterogeneity early on, PEDAL has the potential to improve the drug development process in multiple ways: (1) enable an early view of a drug's therapeutic potential; (2) support the development of targeted therapy for patients with specific biomarkers; and (3) cut cost and increase clinical success rates of drug development. While we recognize Predictive is in its infancy in terms of commercializing the PEDAL platform, its current collaborations and data presentations provide us confidence that its AI model has the potential to sustain longterm revenue growth. We conservatively project Predictive's revenues to grow to \$48M in 2033 from \$1.5M in 2024. With current valuation of \$6M and potential for sustainable revenue growth from 2025 onwards, we believe POAI could be an attractive asset for a long-term investor.

Differentiated training dataset built upon a unique asset set. The key differentiator of the PEDAL platform is Predictive Oncology's biobank of over 150,000 tumor samples across 137 subtypes of tumor and accompanying tumor-drug response data. PEDAL also features a library of over 200,000 pathology slides, many of which have been digitized as images, and over 40,000 tissue blocks. With this set of assets, Predictive Oncology could generate a unique training set of multi-omic, real world human data for its Al models, to predict tumordrug response in silico in weeks, followed by validation in its clinical laboratory improvement amendments (CLIA)-certified wet labs.

Al-centered partnerships and ovarian cancer data provide validation. PEDAL has achieved proof-of-concept from a retrospective study in high grade serous ovarian cancer (HGSC) conducted in collaboration with University of Pittsburgh Medical Center (UPMC) Magee-Womens Hospital. In brief, results from this study imply that PEDAL could be used to identify biomarkers that correlate with different survival outcomes of HGSC patients. Predictive Oncology has two other notable ongoing PEDAL-centered partnerships: 1) with Cvergenx (private) to personalize and optimize radiotherapy dose and identify potential radiosensitizers and radioprotectors, and 2) with Cancer Research Horizons (private) to evaluate preclinical candidates of glutaminase inhibitors for cancer treatment. We believe Predictive has potential to provide a wide range of offerings for its pharmaceutical partners, including Al-based predictions of drug responses, biomarker discovery, drug discovery and repurposing, and target identification.

Early days for Al-based drug development, but full of notable achievements so far. Al-based drug development has been growing at unprecedented speed over the past few years, but the sector is still in its infancy as most Al-derived drugs/ targets have barely entered the clinic. Despite our limited visibility of this sector's long-term potential, increasing evidence has validated the power of Al to accelerate drug development, at least at the level of preclinical research. Some Al-biotech frontrunners, such as Absci (ABSI; Buy), have designed first- or best-in-class candidates with much shorter timelines than traditional approaches. Additionally, Al has gained impressive clinical validation in designing personalized cancer therapy. This is exemplified by the robust Phase 2 data of V940—an Al-designed, neoantigen-targeted cancer vaccine developed by Moderna (MRNA; not rated) and Merck (MRK; not rated)—in adjuvant melanoma. BioNTech (BNTX; Buy; Burns) and Evaxion (EVAX; Buy) have also reported positive early- to mid-stage clinical data of Al-designed cancer therapy in metastatic melanoma and pancreatic cancer. Altogether, these data bolster our confidence in the near-term potential of Al in drug development.

Upside from revenue-generating biologic formulation business. Predictive Oncology has a business segment providing contract services and research of biologic formulation. Its clients are biopharmaceutical companies and academic collaborators. This formulation services provides optimized FDA-approved formulations to improve the stability and solubility of vaccines, antibodies, and other protein therapeutics in a faster and lower cost basis to its customers. Predictive Oncology is servicing FluGen (private) to optimize FluGen's M2SR flu vaccine and is expected to receive part of the \$6.2M Phase 2b grant awarded by the Department of Defense over multiple years. With little visibility into the financial terms of this collaboration agreement, we assume Predictive to receive a portion of the grant in 2024. Predictive Oncology also entered into a collaboration and comarketing agreement with Fujifilm (private) to accurately detect endotoxins in biologic products. We currently do not account for revenues from this collaboration and so future revenue could be upside to our estimates. Since the formulation segment is a small revenue contributor (<10% of total revenue in 2023), we expect the size of potential upside impact to be limited.

Valuation. We are initiating coverage of POAI with Buy rating and a 12-month price target of \$3 per share. We project total revenues of \$1.5M in 2024. We assume all future revenues in 2025 and beyond to be generated by PEDAL-related partnered preclinical programs, with risk-adjusted collaboration revenues of approximately \$9M in 2025, growing to \$48M in 2033. In our financial model, collaboration revenues consist of upfront payments and developmental, regulatory, and commercial milestone payments. We conservatively assume the company would add one partnered program each year between 2025 and 2027, and then add two each year afterwards, reaching four active programs in 2029 and maintaining this number thereafter. We risk-adjust the collaboration revenues by assigning various probabilities of partnerships to individual programs, ranging from 50% to 70%. We also apply a probability of approval of 2% and various phase transition success rates to account for risk associated with preclinical programs. We derive our price target based on a risk-adjusted net present value (rNPV) analysis of projected future revenues, assuming an 12% discount rate and a 0% terminal growth rate. We derive an rNPV of \$72M and add in net pro forma cash and cash equivalents of approximately \$6.2M, to arrive at a 12-month price target of 3.07 per diluted share, which we round to \$3.

Risks. Risks to our Buy rating include: (1) partnership, (2) technology, (3) competition, (4) clinical, (5) regulatory, (6) legal and intellectual property, (7) dilution, and (8) delisting.

Company Overview

Predictive Oncology is a biotech company leveraging artificial intelligence (AI) to support the discovery and development of cancer therapy. The company was founded in 2002 and reincorporated in 2013. It changed its name from Skyline Medical Inc. to Precision Therapeutics in 2018 and to Predictive Oncology in 2019. Predictive's common stock began trading on the NASDAQ Capital Market under the ticker "POAI" from June 13, 2019. Prior to that, its common stock was listed on the NASDAQ Capital Market under the ticker "AIPT" from February 2, 2018 and "SKLN" before February 2, 2018. Predictive Oncology is headquartered in Pittsburgh, Pennsylvania. The company has developed a proprietary Patient-centric Drug Discovery using Active Learning (PEDAL) Al platform that enables prediction of tumor drug response among cancer patients at preclinical stages. By introducing the element of human heterogeneity early in drug development, PEDAL could help to cut cost and increase clinical success rates of drug development, enable early decision of a drug's potential in patients, and/or support the development of targeted therapy for patients with specific biomarkers. PEDAL's differentiated training dataset is built upon the company's extensive biobank of tumor samples, paired patients' drug response data, a library of pathology slides and tissue blocks, and 3D cell culture models. Data from a retrospective study in ovarian cancer provided proof-ofconcept for PEDAL. We expect Predictive Oncology to establish partnerships with biopharmaceutical companies for services such as Al-based predictions of drug responses, biomarker discovery, drug discovery and repurposing, and target identification. We project Predictive Oncology to generate its first risk-adjusted, full-year collaboration revenues of approximately \$9M in 2025, growing to \$48M in 2033. The company also provides contract services and research of biologic formulation, focusing on solubility improvements, stability studies, and protein production for its biopharmaceutical academic clients. Predictive reported cash and cash equivalents of \$5.3M at the end of 2Q24, and raised approximately \$1.3M through exercise of warrants in late July, resulting in a pro forma cash balance of \$6.6M, which we believe is sufficient to fund the company's planned operations into 1H25.

Exhibit 1: The PEDAL AI Platform



Source: Company presentation, July 2024

Investment thesis

Our bullish view on Predictive is based on positive perception of the following factors: (1) PEDAL addresses the challenge of cancer patient heterogeneity at preclinical stage; (2) data in ovarian cancer provides initial validation of PEDAL; (3) Al-enabled drug development is booming; and (4) revenue-generating biologic formulation services and other offerings provide upside potential.

1. PEDAL addresses the challenge of cancer patient heterogeneity at preclinical stage

Predictive Oncology has established a proprietary Al platform, PEDAL, to de-risk and accelerate drug development. PEDAL is a multi-component platform that combines an active learning machine learning model developed at Carnegie Mellon University, a proprietary biobank of tumor samples with accompanying historical drug response data and pathology slides, and clinical laboratory improvement amendment (CLIA)certified wet lab testing capabilities. Unlike traditional approaches and many other AI models that rely heavily, if not exclusively, on data generated in animal models at preclinical stages, PEDAL features a unique strength in that it incorporates "the human element" in preclinical drug development. This allows drug developers to have an early view of a drug candidate's potential in patients with minimal cost and time in silico, The implications are two folds. On one hand, it de-risks the drug development process, allowing candidates with broad therapeutic potential to be prioritized; on the other hand, the knowledge of a drug response among different patients could help to identify precision cancer therapeutics that are tailored to patients' genomic profiles when combined with biomarker studies. Additionally, PEDAL's offerings align with the FDA's acceptance of using non-animal models (NAM) for preclinical studies (2022 FDA Modernization Act 2.0). Despite passage of the Act 2.0, most of R&D research is still relying on animal models, mostly rodents, even though results from these models poorly translate into effective therapies. Only less than 25% of R&D staff in life sciences are familiar with animal model alternatives, according to a recent survey conducted by the non-profit organization Pistoia Alliance. This low utilization of NAM suggests a large untapped market for PEDAL. By addressing the challenge of patient heterogeneity early on, PEDAL has the potential to revolutionize early drug development, in our view.

According to Predictive Oncology, its biobank of over 150,000 tumor samples across 137 subtypes of tumor represents one of the largest privately held commercial banks of tumor samples. At least ten tumor types have a large collection of samples (over 500), including ovarian, lung, colon, breast, and pancreatic cancers. These tumor samples are accompanied with databases of comprehensive drug response data and multiomic tumor data. Additionally, the company houses a library of over 200,000 pathology slides, many of which have been digitized as images, and over 40,000 tissue blocks. The company also launched its organ-specific 3D cell culture models to evaluate drug candidates in environments that closely mimic human tissues. With this set of assets, Predictive Oncology has the ability to predict patient drug response *in silico* in weeks and validate its findings in its CLIA-certified wet labs within three months (Exhibit 2). Although time saving at preclinical stage is not likely to materially shorten the length of the entire drug development process, Predictive's unique assets offer an unparalleled opportunity to gain insights from patient samples at preclinical stage. We believe Predictive has the potential to provide a wide range of offerings including Al-based predictions of drug responses, biomarker discovery, drug discovery and repurposing, and target identification.

PEDAL pre-clinical drug discovery methodology As little as Increased chance of clinical success with Drug and Active Tumor intelligence gathered "Go/ learnings assays Initial data during the prefeatures "No Go months (CORE) (wet lab) (biobank) clinical phase

Exhibit 2: PDEAL Enable Insights of Patient Heterogeneity at Preclinical Stages

Source: Company presentation, July 2024

2. Data in ovarian cancer provides initial validation to PEDAL

Predictive Oncology recently presented positive data from its collaborative study with University of Pittsburgh Medical Center (UPMC) Magee-Womens Hospital using AI to predict survival outcomes of ovarian cancer patients, which we believe serves as the initial proof-of-concept of the company's AI capabilities. The study focused on high grade serous ovarian cancer (HGSC), the most common type of ovarian cancer. HGSC is highly aggressive and accounts for nearly two-thirds of ovarian cancer death.

Most patients are diagnosed at metastatic phase and have limited treatment options. 80% of HGSC patients succumb to the disease in less than 3.5 years and the rest of the patients have long-term survival of over 5 years. It remains unknown if and what genetic biomarkers are correlated with different HGSC survival outcomes.

In this retrospective study, researchers analyzed clinical data and tumor specimens collected between 2010 and 2016, extracted features including exosome profiles, transcriptome profiles, tumor drug responses, and digital pathology data, and used these features as input to train ML models to classify short-term (2yr) versus long-term (5yr) HGSC survivors. Among 160 ML models tested, 20 models predicted with better accuracy than clinical profiles alone. These top-performing models identified features that either negatively or positively correlated with survival (Exhibit 3), providing a list of candidates for future research and development. It is intriguing that short-term and long-term survival correlated with distinct types of features. Specifically, short-term survival seems to be driven by molecular features whereas long-term survival is correlated with predominantly pathology imaging features (Exhibit 4). While the relevance of these early observations needs to be experimentally validated, these data suggest the potential of PEDAL AI to identify biomarkers that could aid in developing targeted therapies and/or identifying patients who are potential drug responders into clinical trials.

Exhibit 3: Features Correlated With Survival Outcomes of HGSC Patients

Top	Top 10 Features – HGSC 2y Surviva									
Rank	Feature	Feature Set								
1	STRN	Whole Transcriptome								
	SMARCE1	Whole Transcriptome								
	FIP1L1	Whole Transcriptome								
4	DCTN1	Whole Transcriptome								
	TSHR	Whole Transcriptome								
	LF39	Whole Exome (Latent Feature)								
7	LF243	Whole Exome (Latent Feature)								
8	LF199	Whole Exome (Latent Feature)								
	FOXO1	Whole Transcriptome								
	LF118	Whole Transcriptome (Latent Feature)								
	40 Fa									
	10 Feature	atures - HGSC 5y Survival								
	The same of the sa	atures – HGSC 5y Survival								
	Feature	atures – HGSC 5y Survival								
Rank	Feature 512_7	reatures - HGSC 5y Survival Feature Set Digital Pathology								
Rank	Feature 512_7 512_28	Feature Set Digital Pathology Digital Pathology								
Rank 1 2	Feature 512_7 512_28 128_23	Feature Set Digital Pathology Digital Pathology Digital Pathology								
Rank	Feature 512_7 512_28 128_23 512_22	Peatures – HGSC 5y Survival Feature Set Digital Pathology Digital Pathology Digital Pathology Digital Pathology								
Rank 1 2 3 4 5	Feature 512_7 512_28 128_23 512_22 Age	Peatures – HGSC 5y Survival Feature Set Digital Pathology Digital Pathology Digital Pathology Digital Pathology Clinical Profile								
Rank 1 2 3 4 5	Feature 512_7 512_28 128_23 512_22 Age 512_1	Features — HGSC 5y Survival Feature Set Digital Pathology Digital Pathology Digital Pathology Digital Pathology Clinical Profile Digital Pathology								
Rank 1 2 3 4 5 6	Feature 512_7 512_28 128_23 512_22 Age 512_1 LF255	Peature Set Digital Pathology Digital Pathology Digital Pathology Digital Pathology Digital Pathology Clinical Profile Digital Pathology Whole Transcriptome (Latent Feature)								

Source: Orr et al. ASCO 2024

Predictive Oncology has established two Al-centered partnerships before the announcement of the ovarian cancer data. In February 2023, the company entered into a partnership with Cvergenx, a private biotech company developing personalized radiotherapy, to use PEDAL Al to personalize and optimize radiotherapy dose and discover/repurpose compounds that can be potential radiosensitizers and radioprotectors. In March 2023, Predictive Oncology partnered with Cancer Research Horizons, a private company operated under Cancer Research UK, to develop oncology drugs utilizing the PEDAL platform. This collaboration aims to use PEDAL to evaluate Cancer Research Horizons' preclinical glutaminase inhibitors in different

cancer types and patient populations. We are encouraged by the wide breadth of partnerships, which exemplified PEDAL's broad capabilities. Although neither deal involves financials, we are optimistic that the proof-of-concept data in ovarian cancer could help to increase awareness of PEDAL and attract pharmaceutical partners.

In our financial model, we assume that Predictive Oncology would receive collaboration revenues for future preclinical programs from its partners beginning in 2025. In our projection, collaboration revenues consist of upfront payments and developmental, regulatory, and commercial milestone payments. Royalty revenues are excluded in our current estimate. We conservatively assume the company would add one partnered program each year between 2025 and 2027, and then add two each year afterwards. Assuming it takes two years for Predictive to complete its responsibility of each program (preclinical development and maybe early clinical POC studies), we project the company to increase the numbers of active collaboration programs from one in 2025 to four in 2029, and maintain four active partnered programs thereafter. We define active programs as preclinical development and maybe early clinical POC studies that Predictive is primarily responsible for in each program. Our estimated deal structure is based on typical transactions in Al-based drug discovery announced in recent years. We risk-adjust the projected revenues by probabilities of partnerships and various transition success rates across phases of drug development. We expect Predictive Oncology to generate its first risk-adjusted, full-year collaboration revenues of approximately \$9M in 2025, growing to \$48M in 2033. Please refer to the Key Model Assumptions for details of risk adjustments and estimated revenues.

3. Al-based drug development is booming

Al holds tremendous promise to revolutionize the process of drug development. Al can process the vast amount of complex biomedical data at unprecedented speed, potentially expediting research and development and lowering its cost. More importantly, Al has the potential to expand the diversity of drug targets and methods to design drugs beyond what has been achieved using traditional approaches. This advantage could help identify novel drug candidates with better profiles and ultimately increase clinical success rates. In addition to target discovery and drug design, Al is also being used at later stages of drug development. Some examples include designing clinical trials, matching patients with treatments, analyzing medical images, and managing clinical data. It is conceivable that Al could be utilized in almost every step of drug development, and healthcare in general, within the next decade. Indeed, we have seen strong growth momentum in this space in the past few years in terms of the number of startups formed and partnerships established with pharmaceutical companies, the breadth of potential Al applications in drug development, and large-cap pharma's devotion to building in-house Al capabilities.

It remains to be seen how much of the claimed benefits of AI are realistic and can be fulfilled, because the utilization of AI in drug development is still in its infancy. Most AI-derived drugs/targets have barely emerged from preclinical studies and so their therapeutic potentials remain to be evaluated and compared to existing therapies. One notable exception, however, is recent progress of AI in personalized cancer therapy. In this space, AI has gained impressive clinical validation, in our view. Specifically, algorithms are used to identify neoantigens from tumors of individual cancer patients and design neoantigen-targeted therapeutic vaccines. Since each person has a distinct set of neoantigens, such cancer vaccines are personalized therapies. Moderna (MRNA; not rated) and Merck (MRK; not rated) have reported compelling Phase 2 data in adjuvant melanoma supporting the potential of their AI-designed, mRNA-based cancer vaccine V940 to boost patients' immune response and prevent disease recurrence when combined with pembrolizumab. V940 is being evaluated in two Phase 3 studies in adjuvant melanoma and certain types of non-small cell lung cancer. Several other players, including BioNTech (BNTX; Buy; Burns) and Evaxion (EVAX; Buy) have also reported positive early- to mid-stage clinical data supporting the value of AI in designing personalized cancer vaccines.

There is also increasing evidence validating the potential of AI to accelerate drug development, at least at the level of preclinical research. This is exemplified by some AI-biotech frontrunners who have designed first- or best-in-class clinical candidates with much shorter timelines than traditional approaches. For example, Absci (ABSI; Buy), a biotech company developing novel biologics by leveraging combined power of AI and synthetic biology, aims to advance its AI-designed anti-TL1A antibody into the clinic in 1H25, two

years after initiating the research program. In contrast, it takes 4~6 years on average to do so with traditional drug R&D. Absci has reported preclinical data demonstrating the best-in-class potential of its antibody against several clinical candidates targeting TL1A, validating the power of its AI and wet lab capabilities.

Differentiation is key for AI-biotech or techbio companies with increasing competition in this space. We believe differentiation is synonymous with quality data and validation. It is important to know if and how a company's dataset is fit for solving a particular problem, as well as how a company addresses data artifacts, uses appropriate controls, and conduct periodic audits. Unfortunately, the degree to which all such information can be disclosed varies due to confidentiality requirements, making it difficult to evaluate and compare different companies. Validation is relatively easier to gauge compared to data. We typically see two forms of validation in the AI-biotech space: experimental (e.g. manuscripts and conference presentations) and partnership validation (e.g. deals, collaborations, and investments).

Overall, we believe the AI wave has generated a lot of industry-transforming possibilities in drug development. The initial achievements from some of the pioneers in this space, although sparse, bolsters our confidence in the near-term potential of AI. However, we anticipate that it will take time—maybe five years or even more—to judge how much of the claimed benefits of AI can be delivered.

4. Revenue-generating biologic formulation services and other offerings provide upside potential.

An analysis of Predictive Oncology's 2023 financials reveals that the company primarily derived its revenue from the Eagan operating segment (\$1.1M, 64% of total revenue) followed by AI offerings (\$493K, 27%) and a biologic formulation segment (\$152K, 9%). In the Eagan segment, Predictive sells the STREAMWAY System and accompanying proprietary solution and filters through its wholly owned subsidiary Skyline Medical. STREAMWAY is an FDA-cleared, automated waste fluid disposal system that disposes potentially infectious medical waste fluids collected during surgical and other procedures. We believe Predictive Oncology could divest Skyline Medical in the near- or mid-term upon achieving profitability with STREAMWAY in order to consolidate its business to focus on AI programs.

Predictive's biologic formulation segment is located in Birmingham, AL. This business segment provides contract services and research of biologic formulation for biopharmaceutical companies and academic collaborators. The services focus on solubility improvements, stability studies, and protein production. In particular, the company provides optimized FDA-approved formulations for vaccines, antibodies, and other protein therapeutics in a faster and lower cost basis to its customers.

The core technology of the biologics formulation services is the company's proprietary automated High Throughput Self-Interaction Chromatography (HSC) platform. This HSC platform is a self-contained, automated system that conducts high-throughput, self-interaction chromatography screens for different excipients previously approved by the FDA for protein formulations. A proprietary Al algorithm is used to analyze data generated from HSC screens to identify the optimal combination(s) of buffers, pH, and excipients, resulting in increased solubility and physical stability of proteins. According to Predictive Oncology, it has successfully increased protein solubility by ten-fold and even hundred-fold for several of their clients.

One customer using Predictive's HSC platform is FluGen, a private biotech company focused on developing novel flu vaccines. In April 2024, FluGen selected Predictive Oncology as a subcontractor to develop FluGen's M2SR flu vaccine. Predictive is responsible for optimizing the stability and solubility of the vaccine product in a refrigerated state using its HSC platform. In return, Predictive is expected to receive part of the \$6.2M Phase 2b grant awarded by the Department of Defense over multiple years. With little visibility into the financial terms of this collaboration agreement, we assume Predictive to receive a portion of the grant in 2024.

During 2Q24 earning call, the company announced its plan to consolidate the operations of the Birmingham laboratory to its headquarter in Pittsburgh. We believe this strategy could help to extend cash runway and expect the Birmingham office to be closed in the near- to mid-term.

Beyond the biologic formulation services, Predictive Oncology also has other offerings, such as a novel EndoPrep™ sample treatment technology. This technology enables accurate detection of endotoxins in biologic products. Endotoxins are components of the cell membrane of gram-negative bacteria and can trigger immune response in patients even at sub-nanogram levels. In April 2024, Predictive entered into a collaboration and co-marketing agreement with FUJIFILM Wako Chemicals U.S.A. Corporation (Fujifilm, private) to reduce protein interference in endotoxin testing of biopharmaceutical products, allowing more accurate detection of endotoxins and improving safety of biologic products. We currently do not account for revenues from this collaboration.

Based on Predictive Oncology's historical revenues—\$1.5M in 2022, \$1.8M in 2023, and \$700K in 1H24—we project total revenues of \$1.5M in 2024, accounting for potential revenues from the current three business segments. Given the uncertainty around the timeline of potential STREAMWAY divesture and relatively small revenue of the formulation segment, we assume all future revenues in 2025 and beyond to be generated by PEDAL-related partnered programs. Revenues from other segments could provide upside to our estimate.

Financials

Revenues. Predictive recorded revenue of \$279K for 2Q24. We expect the company to report total revenues of \$1.5M in 2024. Currently, we project risk-adjusted total revenues to grow to \$48M by 2033.

Net income and EPS. Predictive recorded a net loss of \$3.2M or \$0.68 per share in 2Q24. For 2024, we expect the company to report a net loss of \$11.2M or \$2.03 per diluted share. We expect 2026 to be the company's first year to become profitable with a net profit of approximately \$1.0M or \$0.05 per diluted share. Please refer to the detailed income statement for our estimates of net income and earnings or loss per diluted share for the forecast period, 2024-2033.

Cash. Predictive reported cash and cash equivalents of \$5.3M at the end of 2Q24 and raised approximately \$1.3M through exercise of warrants in late July, resulting in a *pro forma* cash balance of \$6.6M, which we believe is sufficient to fund the company's planned operations into 1H25.

Valuation

We value the shares of Predictive using a risk-adjusted net present value (rNPV) analysis. To account for uncertainties in operations, we used a weighted average cost of capital (WACC) of 12% to discount future revenues.

Key Model Assumptions

In our financial model, we assume that Predictive Oncology would receive collaboration revenues for future preclinical programs from its partners beginning in 2025. In our projection, collaboration revenues consist of upfront payments and developmental, regulatory, and commercial milestone payments. Royalty revenues are excluded in our current estimate. We conservatively assume the company would add one partnered program each year between 2025 and 2027, and then add two each year afterwards. Assuming it takes two years for Predictive to complete its responsibility for each program (preclinical development and maybe early clinical POC studies), we project the company to increase the numbers of active collaboration programs from one in 2025 to four in 2029, and maintain four active partnered programs thereafter. We define active programs as preclinical development and maybe early clinical POC studies that Predictive is primarily responsible for in each program.

Our estimated deal structure is based on typical transactions in Al-based drug discovery announced in recent years (Exhibit 4), which include an average \$20M upfront payment and milestone payments ranging from \$500M to \$1B. To account for risk associated with preclinical stage programs, we apply a probability of approval of 2% and various phase transition success rates to risk-adjust the expected collaboration revenues (Exhibit 4). We also risk-adjust the revenues by assigning various probabilities of partnerships to individual programs based on how far they are from now, with 70% for near-term programs (2025 and 2026),

60% for mid-term programs (2027 and 2028), and 50% for those that are likely to initiate in 2029 and onwards (Exhibit 5).

Exhibit 4: Assumed Deal Structure of Al-Drug Discovery Transactions and Risk Adjustment

Assumed deal stru	cture \$ ('000)
upfront payment	25,000
Preclinical to Phase 1 milestones	25,000
Phase I to II milestone	50,000
Phase II to III milestone	75,000
Phase III to NDA/BLA milestone	100,000
NDA/BLA to approval milestone	100,000
1st sales milestone (1st yr)	150,000
2nd sales milestone (3rd yr)	200,000
3rd sales milestone (5th yr)	200,000
total milestone payments	900,000
Phase transition success rates f	or all disease indications
Preclinical to Phase 1	20%
Phase I to II	52%
Phase II to III	29%
Phase III to NDA/BLA	58%
NDA/BLA to approval	91%
Current Phase	Probability of Approval
Preclinical	2%
Phase I	8%
Phase II	15%
Phase III	52%
NDA/BLA	91%

Source: Clinical development success rates and contributing factors 2011-2020, NIH estimate, Company reports and H.C.Wainwright estimates

Exhibit 5: Risk-Adjusted Al Collaboration Revenues, 2025E-2033E

Risk-Adjusted Collaboration Revenues										
\$ ('000)	POP	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E
Active programs (preclinical and POC clinical)		1	2	2	3	4	4	4	4	4
Assumed price increase per year										
3%										
program 1	70%	9,333	5,833	9,473	-	1,583	-	-	1,224	1,120
program 2	70%		9,613	6,008	9,758	-	1,631	-	-	1,261
program 3	60%			8,487	5,305	8,615	-	1,440	-	-
program 4	60%				8,742	5,464	8,873	-	1,483	-
program 5	60%				8,742	5,464	8,873	-	1,483	-
program 6	50%					7,503	4,690	7,616	-	1,273
program 7	50%					7,503	4,690	7,616	-	1,273
program 8	50%						7,728	4,830	7,844	-
program 9	50%						7,728	4,830	7,844	-
program 10	50%							7,960	4,975	8,080
program 11	50%							7,960	4,975	8,080
program 12	50%								8,199	5,124
program 13	50%								8,199	5,124
program 14	50%									8,445
program 15	50%									8,445
Total Collaboration Revenues (\$ '000)		9,333	15,447	23,969	32,546	36,132	44,213	42,253	46,228	48,226

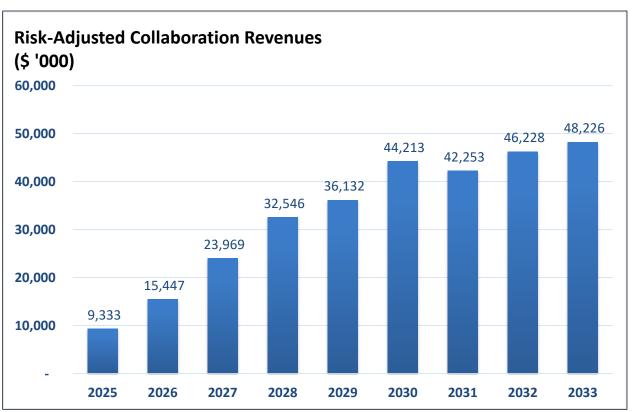
Note: POP, probability of partnerships. Source: H.C. Wainwright estimates

We project total revenues of \$1.5M in 2024, accounting for potential revenues from the current three business segments. Given the uncertainty around the timeline of potential STREAMWAY divesture and

relatively small revenue of the formulation segment, we assume all future revenues in 2025 and beyond to be generated by PEDAL-related partnered programs. We expect Predictive to generate its first risk-adjusted full-year collaboration revenues of approximately \$9M in 2025, growing to \$48M in 2033 at an annual year CAGR of 20% (Exhibit 5 and 6). Potential upside to our estimates includes: (1) earlier- and larger-than-expected deals; (2) accelerated development of programs; (3) larger-than-expected capabilities to conduct more than four programs in parallel; (4) future programs and partnerships that we have not yet included in our projections; and (5) additional HSC-related revenues and potential revenues from other business segments.

In our risk-adjusted net present value (rNPV) model, we used a WACC of 12% as the discount rate and a 0% terminal growth rate to arrive at an rNPV \$72M and add in *pro forma* net cash and cash equivalents of approximately \$6.2M, to arrive at a 12-month price target of \$3.07 per diluted share, which we round to \$3. (Exhibit 7).

Exhibit 6: Risk-Adjusted AI Collaboration Revenues, 2025E-2033E, Graph View



Note: The decrease in projected revenue in 2031 is due to staggered payments for different collaboration programs. Source: H.C. Wainwright estimates

Exhibit 7: Risk-Adjusted NPV Analysis

rNPV Analysis											
\$ ('000)		2024	2025	2026	2027	2028	2029	2030	2031	2032	2033
Gross Revenue		850	9,333	15,447	23,969	32,546	36,132	44,213	42,253	46,228	48,226
COGS		(285)	(2,800)	(4,306)	(6,232)	(7,811)	(7,949)	(8,843)	(8,451)	(8,783)	(8,946)
Net Revenue		565	6,533	11,141	17,737	24,735	28,183	35,370	33,802	37,445	39,280
Operating Expenses		(4,383)	(8,807)	(10,094)	(11,493)	(13,799)	(16,629)	(19,497)	(22,100)	(24,427)	(27,073)
Operating Income		(3,818)	(2,273)	1,047	6,244	10,936	11,554	15,873	11,703	13,018	12,208
Tax		-	-	-	-	-	-	-	-	-	-
Net Income		(3,818)	(2,273)	1,047	6,244	10,936	11,554	15,873	11,703	13,018	12,208
Periods		0	0.5	1.5	2.5	3.5	4.5	5.5	6.5	7.5	8.5
Discount Rate	12.0%	1.00	0.94	0.84	0.75	0.67	0.60	0.54	0.48	0.43	0.34
Discounted Income		(3,818)	(2,148)	884	4,704	7,355	6,938	8,511	5,602	5,564	4,118
								Terminal gro	owth rate	0.0%	
Total rNPV	72,030							Terminal val	lue	101,729	
pro forma Net Cash	\$ 6,206							Discounted '	TV	34,320	
# of Shares ('000)	25,468										
Price per share (\$)	3.07										

Source: H.C. Wainwright estimates

Risk Analysis

In addition to the typical risks associated with biotech companies, the risks specific to Predictive to be considered are as follows:

Partnership risk. We expect the majority of Predictive's future revenues to derive from collaboration revenue payments from its partners. If the company is unable to establish new partnerships or complete preclinical studies under existing partnerships, its potential to generate future revenues could be adversely impacted. Additionally, if Predictive's partners do not advance the drug candidates into clinical development, the company may not be able to receive milestone payments or royalties.

Technology risk. The quality of Predictive's AI models is critical to its potential to establish and maintain partnerships. Data generated from PEDAL is still at early stage and needs to be validated with preclinical, if not clinical studies. Additionally, it is possible that quality of the future collaborative programs may not meet its partners' expectations, which could harm the company's ability to generate revenues.

Competition risk. Predictive could face significant competition from competitors who can build larger or better Al models. Such competitive pressure could adversely impact Predictive's potential to establish partnerships.

Clinical risk. Predictive's partners are required to successfully complete clinical studies to secure marketing approvals in the U.S. and other geographic regions. Clinical studies are inherently risky due to variability in patients' disease conditions and clinical delays could negatively impact Predictive's future revenues.

Regulatory risk. Clinical advancement of Predictive's collaborative programs is subject to FDA regulation. The regulatory approval process of the FDA is lengthy and inherently unpredictable. If Predictive's partners are not able to obtain, or if there are delays in obtaining regulatory approvals, Predictive's potential to generate revenues could be adversely impacted.

Legal and intellectual property risk. Licensing of intellectual property is critical to Predictive's business. We expect the company to enter licensing agreements with future partners. If Predictive fails to comply with its obligations under any licensing or collaboration agreements, it may be required to pay damages and could lose intellectual property rights. Such an event could adversely affect its business.

Dilution risk. The company may raise capital through additional equity financings, which may result in diluted ownership interest.

Delisting risk. Predictive Oncology's common stock could be delisted from the Nasdaq Capital Market if the company fails to comply with the minimum closing bid price requirement under NASDAQ Marketplace Rule 5550(a)(2) and fails to regain compliance by maintaining a closing bid price of at least \$1.00 for a minimum of 10 consecutive trading days within 180 days of receiving the notice from the Listing Qualifications Department of Nasdaq. Delisting could result in inaccurate quotations on the price of the company's common stock.

Predictive Oncology

Income Statement

FY December 31

\$ ('000)	FY 2022A	1Q23A	2Q23A	3Q23A	4Q23A	FY 2023A	1Q24A	2Q24A	3Q24E	4Q24E	FY 2024E	FY 2025E
Revenue	1,505	240	490	715	335	1,780	420	279	500	350	1,548	9,333
Total Revenue	1,505	240	490	715	335	1,780	420	279	500	350	1,548	9,333
Cost of sales	505	120	160	107	248	635	187	153	75	210	625	2,800
Gross profit	1,000	120	330	608	87	1,145	232	126	425	140	923	6,533
General and administrative expense	11,111	2,336	2,705	2,584	1,804	9,428	2,627	2,137	1,496	898	7,158	4,155
Operations expense	3,798	879	993	843	1,413	4,127	1,102	893	804	724	3,523	3,533
Sales and marketing expense	1,359	370	429	336	375	1,511	740	284	228	234	1,486	1,118
Loss on impairment of goodwill	7,231	-	-	-	-	-	-	-	-	-	-	-
Loss on impairment of finite-lived intangible assets	3,349	-	-	-	-	-	-	-	-	-	-	-
Loss on impairment of property and equipment	185	-	163	-	-	163	-	-	-	-	-	-
Operating loss	(26,034)	(3,465)	(3,959)	(3,154)	(3,506)	(14,084)	(4,237)	(3,189)	(2,103)	(1,716)	(11,244)	(2,273)
Other income	186	42	29	48	34	153	19	9	-	-	28	-
Other expense	(5)		-	(61)	(4)	(65)	(2)	(2)	-	-	(4)	-
Gain on derivative instruments	116	1	7	3	1	12	1	0	-	-	1	-
Loss before income taxes	(25,738)	(3,422)	(3,923)	(3,163)	(3,475)	(13,984)	(4,219)	(3,181)	(2,103)	(1,716)	(11,218)	(2,273)
Income tax benefit (expense)	-	-	-	-	-	-	-	-	-	-	-	-
Net loss	(25,738)	(3,422)	(3,923)	(3,163)	(3,475)	(13,984)	(4,219)	(3,181)	(2,103)	(1,716)	(11,218)	(2,273)
Basic EPS	(6.98)	(0.86)	(0.98)	(0.78)	(0.86)	(3.48)	(1.04)	(0.68)	(0.32)	(0.26)	(2.03)	(0.17)
Diluted EPS	(6.98)	(0.86)	(0.98)	(0.78)	(0.86)	(3.48)	(1.04)	(0.68)	(0.32)	(0.26)	(2.03)	(0.16)
Basic Shares Outstanding ('000)	3,686	3,968	3,997	4,031	4,063	4,015	4,063	4,665	6,667	6,667	5,515	13,167
Diluted Shares Outstanding ('000)	3,686	3,968	3,997	4,031	4,063	4,015	4,063	4,665	6,667	6,667	5,515	13,867

Source: Company reports and H.C. Wainwright estimates.

Predictive Oncology Income Statement

FY December 31

\$ ('000)	FY 2022A	FY 2023A	FY 2024E	FY 2025E	FY 2026E	FY 2027E	FY 2028E	FY 2029E	FY 2030E	FY 2031E	FY 2032E	FY 2033E
Revenue	1,505	1,780	1,548	9,333	15,447	23,969	32,546	36,132	44,213	42,253	46,228	48,226
Total Revenue	1,505	1,780	1,548	9,333	15,447	23,969	32,546	36,132	44,213	42,253	46,228	48,226
Cost of sales	505	635	625	2,800	4,306	6,232	7,811	7,949	8,843	8,451	8,783	8,946
Gross profit	1,000	1,145	923	6,533	11,141	17,737	24,735	28,183	35,370	33,802	37,445	39,280
General and administrative expense	11,111	9,428	7,158	4,155	4,771	5,407	6,377	7,530	8,442	9,546	10,605	11,774
Operations expense	3,798	4,127	3,523	3,533	4,135	4,813	6,004	7,580	9,413	10,777	11,900	13,239
Sales and marketing expense	1,359	1,511	1,486	1,118	1,188	1,272	1,417	1,518	1,643	1,777	1,922	2,060
Loss on impairment of goodwill	7,231	-	-	-	-	-	-	-	-	-	-	-
Loss on impairment of finite-lived intangible assets	3,349	-	-	-	-	-	-	-	-	-	-	-
Loss on impairment of property and equipment	185	163	-	-	ı	-	-	ı	-	-	-	-
Operating loss	(26,034)	(14,084)	(11,244)	(2,273)	1,047	6,244	10,936	11,554	15,873	11,703	13,018	12,208
Other income	186	153	28	-	-	-	-	-	-	-	-	-
Other expense	(5)	(65)	(4)	-	-	-	-	-	-	-	-	-
Gain on derivative instruments	116	12	1	-	-	-	-	-	-	-	-	-
Loss before income taxes	(25,738)	(13,984)	(11,218)	(2,273)	1,047	6,244	10,936	11,554	15,873	11,703	13,018	12,208
Income tax benefit (expense)	-	-	-	-	-	-	-	-	-	-	-	-
Net loss	(25,738)	(13,984)	(11,218)	(2,273)	1,047	6,244	10,936	11,554	15,873	11,703	13,018	12,208
Basic EPS	(6.98)	(3.48)	(2.03)	(0.17)	0.06	0.28	0.48	0.51	0.70	0.52	0.57	0.54
Diluted EPS	(6.98)	(3.48)	(2.03)	(0.16)	0.05	0.25	0.43	0.45	0.62	0.46	0.53	0.51
Basic Shares Outstanding ('000)	3,686	4,015	5,515	13,167	18,917	22,667	22,667	22,667	22,667	22,667	22,667	22,667
Diluted Shares Outstanding ('000)	3,686	4,015	5,515	13,867	19,617	25,468	25,468	25,468	25,468	25,468	24,768	24,067

Source: Company reports and H.C. Wainwright estimates.

Predictive Oncology

Balance :	Sheet
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\$ ('000)	1Q23A	2Q23A	3Q23A	4Q23A	FY 2023A	1Q24A	2Q24A
Current Assets							
Cash	18,597	14,764	11,915	8,729	8,729	5,197	5,332
Accounts receivable	283	431	545	334	334	509	387
Inventories	380	394	440	494	494	442	568
Prepaid expense and other assets	520	381	621	522	522	413	598
Total Current Assets	19,780	15,970	13,520	10,078	10,078	6,561	6,885
Property and equipment, net	1,772	1,549	1,393	1,234	1,234	1,088	910
Intangibles, net	273	266	259	252	252	246	239
Lease right-of-use assets	3,063	3,008	2,870	2,728	2,728	2,582	2,432
Other long-term assets	174	174	124	124	124	124	121
Total Non-current Assets	5,281	4,997	4,646	4,339	4,339	4,040	3,702
Total Assets	25,062	20,967	18,167	14,417	14,417	10,601	10,587
Current liabilities							
Accounts payable	1,424	1,013	1,168	1,342	1,342	1,729	1,563
Note payable	1,424	1,013	260	150	150	38	277
Accrued expenses and other liabilities	1,406	1,650	1,811	1,632	1,632	1,905	1,947
Derivative liability	13	6	2	1,002	1,002	0	0
Contract liabilities	639	628	375	308	308	304	270
Lease liability	428	466	556	517	517	540	562
Total current liabilities	3,910	3,763	4,172	3,951	3,951	4,517	4,619
Other long-term liabilities	-	-	-	5	5	4	14
Lease liability – net of current portion	2,597	2,499	2,344	2,189	2,189	2,027	1,861
Total Liabilities	6,507	6,262	6,516	6,145	6,145	6,548	6,493
Stockholders' equity:							
Preferred stock	1	_	_	-	_	_	<u>-</u>
Series B Convertible Preferred Stock	1	1	1	1	1	1	1
Common stock	40	40	40	41	41	41	57
Additional paid-in capital	175,713	175,787	175,897	175,992	175,992	175,993	179,198
Accumulated deficit	(157,200)	(161,123)			(167,762)		(175,162)
Total Shareholders' Equity	18,554	14,705	11,651	8,272	8,272	4,054	4,094
Total Liabilities and Stockholders' Equity	25,062	20,967	18,167	14,417	14,417	10,601	10,587

Source: Company reports.

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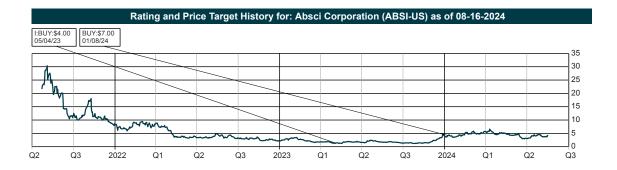
RETURN ASSESSMENT

Market Outperform (Buy): The common stock of the company is expected to outperform a passive index comprised of all the common stock of companies within the same sector.

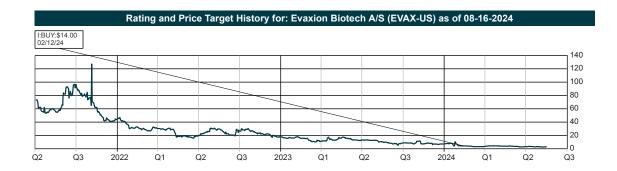
Market Perform (Neutral): The common stock of the company is expected to mimic the performance of a passive index comprised of all the common stock of companies within the same sector.

Market Underperform (Sell): The common stock of the company is expected to underperform a passive index comprised of all the common stock of companies within the same sector.









Related Companies Mentioned in this Report as of August/16/2024							
Company	Ticker	H.C. Wainwright	12 Month	Price	Market		
		Rating	Price Target		Cap		
Absci Corporation	ABSI	Buy	\$7.00	\$4.01	\$455		
BioNTech SE	BNTX	Buy	\$113.00	\$85.19	\$20255		
Evaxion Biotech A/S	EVAX	Buy	\$14.00	\$3.21	\$17		

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Distribution of Ratings Table as of August 16, 2024								
IB Service/Past 12 Month								
Ratings	Count	Percent	Count	Percent				
Buy	559	88.03%	124	22.18%				
Neutral	71	11.18%	3	4.23%				
Sell	0	0.00%	0	0.00%				
Under Review	5	0.79%	1	20.00%				

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