Category

Best Digital Health Solution

General Information

Company Name *

First Ascent Biomedical Inc

Number of employees *

11-50

Turnover and/or Funding

The First Ascent platform has been developed, validated, and deployed through over $10 million in public funding and private grant support, spanning five clinical studies focused on relapsed and refractory cancer patients. These studies have established both the clinical feasibility and the patient impact of First Ascent's Functional Precision Medicine approach across 43 unique cancer types in adult and pediatric populations.

In addition to non-dilutive public and philanthropic support, First Ascent has raised $6 million in private capital to launch a CLIA-certified commercial laboratory in Miami, Florida, set to open in 2025. The company also received a $2 million Florida Innovation Grant to expand access to personalized cancer care for patients across the state, with a focus on underserved and rural communities.

To meet growing national demand, First Ascent is also partnering with Gannon University, the State of Pennsylvania, and philanthropic donors to establish a second precision oncology lab in Erie, PA-further expanding its geographic reach and enabling high-throughput clinical testing and workforce development across the Mid-Atlantic region.

This funding structure reflects strong public-private alignment and a scalable, mission-driven path toward nationwide impact.

words remaining :

317

Product/Solution Name *

xDRIVE/DxPP

Corporate Name *

First Ascent Biomedical

Date of Approval *

2024-01-31

Indications *

Transforming Cancer Care Through Functional Precision Medicine: A Clinically-Validated Platform for Personalized Therapy

Despite remarkable advances in cancer diagnostics and therapeutics, the stark reality remains: in 2025, one in three Americans diagnosed with cancer-over 600,000 people-and nearly 10 million globally will die from the disease. These are not just numbers-they are mothers, fathers, children, patients for whom the "standard of care" is too often ineffective, especially after relapse.

Functional Precision Medicine (FPM) offers a transformative approach to this crisis. Unlike traditional precision oncology, which relies solely on static genomic markers, FPM integrates dynamic ex vivo drug sensitivity testing (DST) of patient-derived tumor cells with genomic profiling to identify the most effective, personalized treatment options, often when no standard options remain.

In a groundbreaking clinical study funded by the Live Like Bella® Pediatric Cancer Research Initiative and published in Nature Medicine, we demonstrated the power of this approach in pediatric patients with relapsed or refractory cancers-an underserved population facing some of the most dismal outcomes. Our prospective study tested the feasibility of returning real-time FPM-based treatment recommendations to a multidisciplinary tumor board within a clinically actionable window (<4 weeks), and evaluated outcomes across a spectrum of rare and aggressive pediatric malignancies.

The results were striking: 83% of patients receiving FPM-guided therapy achieved at least a 1.3-fold improvement in progression-free survival compared to their prior line of treatment. Objective response rates and overall clinical benefit were significantly higher than those observed in non-FPM-guided patients, demonstrating that even in the most challenging cases, FPM can shift the trajectory of care.

Our proprietary xDRIVE platform, validated across 21 unique pediatric and 26 adult cancer types, enables high-throughput, high-resolution DST on both solid and liquid tumors, overcoming longstanding technical barriers that have hindered clinical adoption of earlier-generation chemosensitivity assays. Unlike legacy models, First Ascent's platform leverages advanced cell enrichment, automation, and AI/ML-informed analytics to deliver robust, reproducible insights into tumor-specific drug vulnerabilities.

FPM is no longer a theoretical concept-it is a validated, scalable clinical tool. And in a world where cancer remains one of the leading causes of death, it presents a global opportunity to redefine how we treat patients, not by disease category, but by what actually works for them.

This is not just a new platform-it is a new standard.

words remaining :
123

Therapeutic Areas *

This platform has been prospectively validated across 43 distinct cancer types, spanning both solid tumors and hematologic malignancies, in adult and pediatric patients for whom the standard of care has failed. These include ultra-rare and aggressive relapsed/refractory cancers where no actionable biomarkers or effective treatments remained. The technology has demonstrated clinical feasibility and impact in central nervous system tumors, sarcomas, leukemias, lymphomas, neuroblastoma, medulloblastoma, osteosarcoma, pancreatic, colorectal, breast, and lung cancers, among others.

By uncovering functional drug sensitivities beyond genetic drivers, the platform enables tailored treatment strategies across a wide spectrum of high-mortality, high-complexity diseases, precisely where conventional approaches fall short.

words remaining :

399

*Kindly clearly label your files with company name and asset name.

Background information and need for drug / device
(please be as specific as possible in your description; limit 500 words)

First Ascent Biomedical - Redefining Cancer Therapy Through Functional Precision Medicine

First Ascent Biomedical is pioneering a transformative approach to cancer treatment through its proprietary Functional Precision Medicine (FPM) platform. Unlike traditional precision oncology, which relies heavily on static genomic profiling, FPM integrates live drug sensitivity testing (DST) of patient-derived tumor cells with genomic and molecular insights to uncover real-time vulnerabilities in each patient's cancer. The result is a dynamic, patient-specific map of which drugs, or combinations, are most likely to be effective.

This platform has been clinically validated in both pediatric and adult cancers, with prospective use in 43 unique tumor types, including both liquid and solid malignancies, where standard therapies have failed. In a landmark study funded by the Live Like Bella® Pediatric Cancer Research Initiative and published in Nature Medicine, 83% of relapsed or refractory pediatric cancer patients experienced a greater than 1.3-fold improvement in progression-free survival (PFS) on FPM-guided therapy compared to their prior treatments. These results represent one of the strongest clinical demonstrations to date of the power of functional drug profiling in improving patient outcomes.

At the core of the platform is xDRIVE™ (ex vivo Drug Response Identification and Validation Engine), which enables high-throughput, high-content testing of 150+ FDA-approved oncology drugs and combinations against a patient's own tumor cells, within a clinically actionable timeframe, in <10 days. Using advanced cell-enrichment techniques, proprietary 3D culture models, and machine-learning analytics, First Ascent generates robust functional data even from small or rare biopsy samples. The platform supports local and remote testing models, including through a growing network of CLIA-certified laboratories.

Key differentiators include:

Proven clinical benefit in real-world, relapsed patient populations

Scalability and reproducibility through automation and AI-based analytics

Compatibility with liquid and solid tumors from both children and adults

Integration with molecular data to support label expansion and biomarker discovery

This approach addresses one of the most critical unmet needs in oncology: identifying viable treatment options when standard therapies fail and no clear biomarkers exist. By treating the tumor as it behaves, rather than solely as it is genetically defined, First Ascent's platform enables actionable, individualized treatment strategies that go beyond the genomic blueprint.

Beyond its clinical application, the platform is already supporting pharmaceutical partnerships, label expansion strategies, and health economic studies with insurers and hospital systems. It is particularly suited for rare, refractory, or off-label use cases where traditional clinical trials are impractical or unavailable.

In a world where one in three U.S. cancer patients and over 10 million globally will die each year despite access to "standard of care," First Ascent's Functional Precision Medicine platform offers a new paradigm, grounded in biology, powered by data, and centered around the individual patient.

words remaining :

53

*Kindly clearly label your files with company name and asset name.

History of the development of the solution/product *
(please be as specific as possible in your description; 500 words)

Clinical and Development Evidence for the First Ascent xDRIVE™ Platform

The xDRIVE™ platform (ex vivo Drug Response Identification and Validation Engine) by First Ascent Biomedical represents a clinically validated, next-generation Functional Precision Medicine (FPM) approach that identifies personalized cancer treatments through real-time testing of live patient tumor cells against a panel of 150+ FDA-approved oncology drugs and combinations. The platform is the result of over a decade of development, with a focus on solving the limitations of genomic-only approaches and overcoming the technical barriers that hindered the routine clinical use of chemosensitivity assays in the past.

xDRIVE™ was first evaluated through a prospective, multi-institutional pediatric cancer study funded by the Live Like Bella® Pediatric Cancer Research Initiative and published in Nature Medicine (April 2024). This groundbreaking study enrolled children and adolescents with relapsed or refractory cancers, patients with no remaining standard-of-care options. Tumor samples were processed using First Ascent's proprietary workflow, including cell enrichment, short-term culture, and high-throughput drug sensitivity testing integrated with molecular profiling. The results were reviewed by a multidisciplinary FPM Tumor Board.

The study achieved its primary endpoint: feasibility of returning treatment recommendations within a clinically actionable timeframe (under 10 days). Most notably, 83% of patients who received xDRIVE™-guided treatment experienced a >1.3× improvement in progression-free survival compared to their most recent prior therapy. Objective response rates and disease control rates were also significantly

improved in patients who received FPM-guided treatment compared to those who did not receive FPM-recommended treatment. These results represent one of the most robust demonstrations to date of the predictive value of ex vivo drug sensitivity in pediatric oncology.

From a development perspective, xDRIVE™ incorporates several novel technical and methodological advancements:

Scalable Automation: The platform utilizes high-throughput liquid handling systems and AI-driven curve fitting to minimize turnaround time and reduce human variability.

Miniaturized Assays: Small sample volume requirements enable testing from core biopsies or resections, broadening clinical applicability.

3D and Co-culture Capabilities: Custom culture models enhance physiological relevance, supporting drug-response fidelity in both solid and hematologic malignancies.

Integrated Genomic Overlay: The DST results are layered with genomic and transcriptomic data, allowing both biology-driven drug selection and mechanistic biomarker discovery.

To date, the xDRIVE™ platform has been prospectively validated across 43 distinct cancer types, including rare and ultra-rare subtypes in both adult and pediatric populations. It has been implemented in multiple U.S. hospital systems and is expanding into a nationwide network of CLIA-certified laboratories, with the first Miami-based lab expected to be operational in early 2025.

In addition to the clinical study in Nature Medicine, the platform is being used in five ongoing clinical studies, with three more set to launch in 2025, including collaborations with major cancer centers. The platform has shown strong alignment between ex vivo drug sensitivity and real-world patient outcomes, confirming its translational validity.

Taken together, the xDRIVE platform offers rigorous, reproducible, and impactful clinical data that support its use as a frontline decision-support tool in advanced cancer care, representing a validated, scalable, and lifesaving innovation in oncology.

words remaining :

2

*Kindly clearly label your files with company name and asset name.

Why this drug or device is innovative, the broad implications for future research, and/or how it will improve the human condition *

Innovation, Future Impact, and Human Benefit of the First Ascent xDRIVE™ Platform

The First Ascent xDRIVE™ platform represents a fundamental innovation in oncology, one that redefines how treatment decisions are made when lives hang in the balance. At its core, xDRIVE™ enables a functional precision medicine approach that directly tests a patient's live tumor cells against a library of more than 150 FDA-approved drugs and combinations to identify the most effective treatments in real time. A treatment plan as individualized as the patient's fingerprint. This is not

theoretical; it's tangible, patient-specific evidence guiding therapy after genomics alone has failed and helping patients today.

Historically, precision oncology has relied heavily on genomic biomarkers to guide treatment. Yet for most cancer patients, especially those with rare, relapsed, or refractory tumors, no actionable mutation is found, or available therapies prove ineffective. xDRIVE™ closes this critical gap by capturing how the tumor behaves, not just how it's built. The ability to functionally screen live cancer cells within days of biopsy, with results returned in under 10 days, is a paradigm shift in personalized medicine.

What makes xDRIVE™ innovative isn't just what it does-it's how it overcomes longstanding barriers that have blocked clinical implementation of ex vivo drug testing for decades. Using novel tumor enrichment protocols, miniaturized 3D culture systems, and AI/ML-driven data analytics, xDRIVE™ generates robust drug-response profiles from even small, heterogeneous samples. The platform is high-throughput, automatable, reproducible, and validated for both liquid and solid tumors in children and adults. It bridges functional testing with genomics to enable mechanism-of-action insights, biomarker discovery, and drug repurposing at scale.

The implications for future research are vast. xDRIVE™ can power label expansion for existing drugs, identify effective drug combinations outside of clinical trial constraints, and rapidly generate evidence for off-label reimbursement. Its ability to functionally evaluate tumor response supports smarter trial design, patient stratification, and even predictive screening for clinical trial enrollment, a major bottleneck in oncology R&D. With centralized CLIA-certified hubs and distributed biopsy collection models, xDRIVE™ can support large-scale multi-site studies and longitudinal tracking of tumor evolution over time.

But perhaps most compelling is its potential to dramatically improve the human condition. In a world where over 10 million people will die of cancer this year, and where treatment is often guided by guesswork or outdated algorithms, xDRIVE™ brings clarity, precision, and hope. In our published clinical study, 83% of children with relapsed cancer treated using xDRIVE™-guided recommendations lived longer than they had on their previous therapy. That's not just innovation, that's impact.

By transforming the treatment decision process from reactive to data-driven, xDRIVE™ empowers oncologists, informs families, and gives patients, especially those with no options left, a second chance. As the platform expands, it will not only inform individual treatment decisions but also reshape how the world discovers and delivers cancer therapies, closing the gap between innovation and access.

words remaining :

24

*Kindly clearly label your files with company name and asset name.

Please provide appropriate references (PubMed, Abstract, Website) *

Functional Testing

https://www.nature.com/articles/s41591-024-02848-4

https://pmc.ncbi.nlm.nih.gov/articles/PMC8563073/?utm_source=Other&utm_medium=rss&utm_content=0-U1gyUXk3Zf8Fys0lOFrfgdFsSDnChs8QdI0aIaSSN&ff=20211118020215&v=2.15.0

https://ar.iiarjournals.org/content/39/8/4023.short

https://ashpublications.org/blood/article/126/23/1352/104628/A-Patient-Specific-Ex-Vivo-Screening-Platform-for

AI/ML

https://pubmed.ncbi.nlm.nih.gov/31208434/

https://pubmed.ncbi.nlm.nih.gov/32565715/

https://pubmed.ncbi.nlm.nih.gov/25939062/

https://currentprotocols.onlinelibrary.wiley.com/doi/abs/10.1002/cpz1.269

Clinical Trials

https://clinicaltrials.gov/study/NCT05857969?term=NCT05857969&rank=1

https://www.clinicaltrials.gov/study/NCT06024603

https://www.clinicaltrials.gov/study/NCT03860376

https://clinicaltrials.gov/study/NCT04956198

https://scottrmackenziefoundation.com/scott-r-mackenzie-foundation-awards-350000-in-support-of-two-year-clinical-trial/

*Kindly clearly label your files with company name and asset name.