Our Cancer Research Backstory And Why It Matters

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Presented By:
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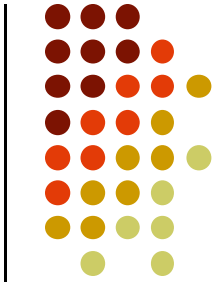
Learning Objectives



- Gain a lay person's understanding of our anti-cancer drug research
- Understand the importance of the next phases of work and how they could increase odds of success and reduce risk of failure
- Appreciate DBX-31's potential impact as an investment and cancer treatment

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Fundraising Milestones – What Happens?

If Amount Raised by Deadline Date:	What happens to your investment?	Plans For Using Funds
<$10,000	It fails to meet the minimum target and gets refunded to you.	No money is received. No plans for use.
$10,000 – $120,000	The minimum target (or more) is reached and your money gets transferred to us.	Although we will receive the investment proceeds, the raised amount will need to be supplemented by more funds from other sources to achieve a meaningful R&D milestone.
$120,000 – $1,070,000	The minimum “useful amount” is reached and your money gets transferred to us.	At the lower end of this range, the raised amount can be supplemented by financing from founders to achieve basic R&D goals. At the upper end, advanced R&D goals plus veterinary clinical trials should be possible.

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Problem #1

Cancer still attacks:
-17M/yr. – globally
-**9.5M**/yr. die – globally
-1.6 million/yr.– USA
-**600,000**+/yr. die – USA

Standard Treatment Options

- Surgery – death, disfigurement; loss of desirable organs/functions
- Radiation – death, painful/durable side effects
- Chemo – death, painful/durable side effects

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Problem #2

- **Dogs** have more cancer than do humans:

- 35x more skin cancer*
- 4x as many breast tumors*
- 8x bone cancer*
- Twice the rate of leukemia*

- Cancer is a leading killer of the **67 million** pet dogs in the **U.S.**

- **More** treatment options are needed

(*Texas A&M Veterinary School)

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The Common Solution

DBX-31 is a unique, naturally occurring bio-molecule that exclusively attacks a wide range of cancers through targeted extrinsic apoptosis (i.e. “cell suicide”) ⟶ superior method compared to other anticancer agents.

We project that it can be commercially synthesized, cost effective, safer, and have broader applications than current treatment options.

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Mini-Biology Lesson

Apoptosis:

ap·op·to·sis. *a-pəp-tō-səs*\ *n.* a process of cell self-destruction that is marked by the fragmentation of nuclear DNA —called also *programmed cell death* or *cell suicide.* Apoptosis is the preferred way to kill cells. *Extrinsic apoptosis is hard to achieve but is regarded as the "holy grail' of cancer treatment*.

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Mini-Biology Lesson

KEY TAKEAWAY

Extrinsic apoptosis is regarded as the "holy grail' of cancer treatment.

SO WHAT?

DBX-31 induces extrinsic apoptosis!

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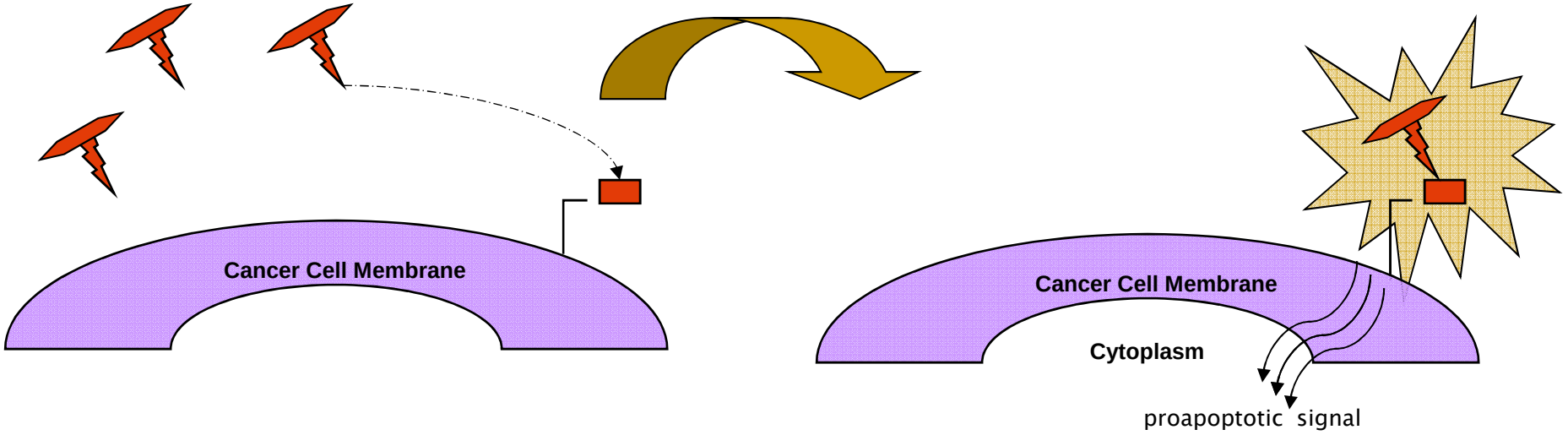
How DBX-31 Works

Observed and Expected Properties

DBX-31 = **Targeting Protein** + **Target Antigen aka "Death" Receptor** = **DBX-31R**



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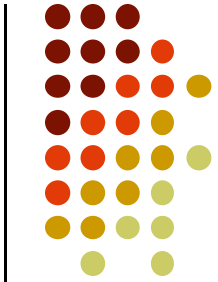
Pre-Clinical Research Results

In Vitro Bioassays Conducted at Cornell University



- Types of Human Cancer Cell Lines Tested:

  - **|| Breast Cancer || HER2 + || Metastatic – Advanced Stage ||**
  - **|| Breast Cancer || Triple Negative || Primary Tumor – Advanced Stage ||**
  - **|| Breast Cancer || Triple Negative || Metastatic – Adv. (epithelial) Stage ||**
  - **|| Breast Cancer || Triple Negative || Metastatic – Adv. (mesenchymal) Stage ||**
  - **|| Ovarian Cancer || Adenocarcinoma || Metastatic – Advanced Stage ||**
  - **|| Colorectal Cancer || Adenocarcinoma || Primary Tumor – Advanced Stage ||**
  - **|| Lung Cancer || Small Cell Carcinoma || Primary Tumor – Advanced Stage ||**
  - **|| Skin Cancer || Uterine origin || Metastatic – Adv. (epithelial) Stage ||**

Notable Points:

These were extremely resistant/untreatable advanced stage, metastatic, cancer cell lines.
Result = average of 3 trial tests for each cell line to ensure reliability.

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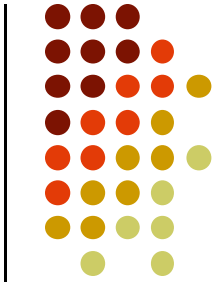
Pre-Clinical Research Results



Key Results:

- Apoptosis induced in **ALL** cancer cell lines

- Apoptotic Index = 42-90+% dead after 72 hr. incubation. (Note: 2 cell lines >95%).
  Extrapolation = 99.99% dead after 96 hr.

- **NO** adverse effects on normal cells

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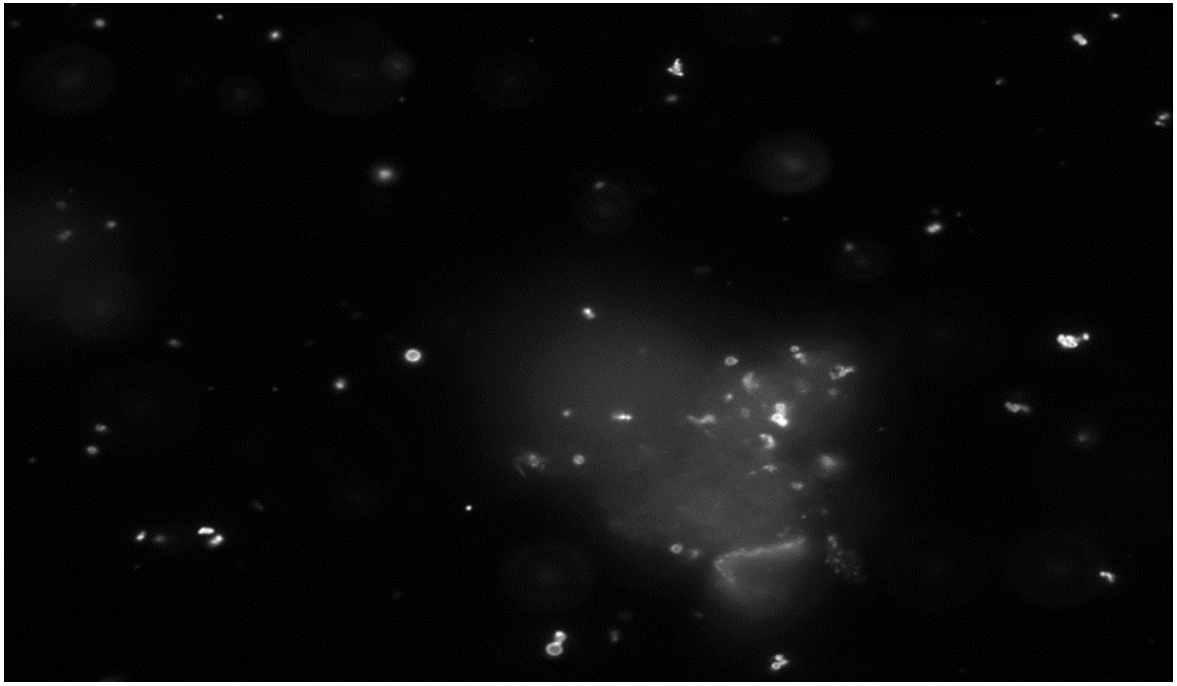
Pre-Clinical Research Results



Photomicrograph 1c – DBX31 vs. Metastatic Breast Cancer

Cellular disintegration. Scattered apoptotic debris.

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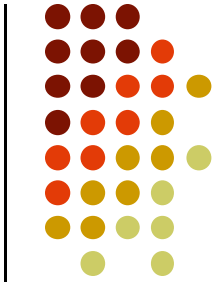
Showcase Experiment



DBX-31

vs.

SKOV-3

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Showcase Experiment

SKOV-3 is an ovarian cancer cell line used as a negative control to test the presence or absence of p53. This means that it is virtually invincible to apoptotic drugs and toxins, including a lethal cytotoxin used as a bioweapon:

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Showcase Experiment

Table 1 *Sensitivity of tumor cell lines to various cytotoxic agents*

The symbol (+) signifies sensitivity and (−), resistance to lysis by the agent.

Cell line	Origin	Sensitivity to			
		TNF	DTX/ricin	ADM	CDDP
222	Ovarian tumor	+	+	+	+
222TR	Ovarian tumor	−	+	+	+
SKOV-3	Ovarian tumor	−	−	−	−
A2780	Ovarian tumor	+	+	+	+
AD10	Ovarian tumor	+	+	−	−
C30	Ovarian tumor	+	+	+	−
U937	Promonomyelocytic	+	+	+	+
Raji[a]	B-cell lymphoma	−	+	+	+

[a] Raji is the only line that is negative for TNF receptor expression on the membrane.

SKOV-3 Ovarian Cancer vs. The Most Powerful Cytotoxins

SKOV-3 is stubbornly resistant to the most lethal, powerful cytotoxic agents/bioweapons (DTX/ricin)

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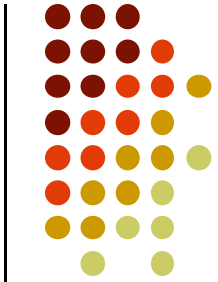
Showcase Experiment Result



- DBX-31 caused robust apoptosis in SKOV-3 cells where **ALL** other cytotoxic agents, including DTX/ricin, **FAILED**
- >80% of cancer cells killed after only 72 hours
- **NO** adverse effects on normal cells

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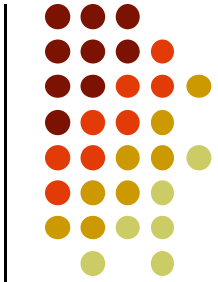
Experimental Conclusion



DBX-31
outperformed 2 of the top selling chemotherapies and a BIOWEAPON

(…but only killed cancer cells!)

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How Other Treatments Compare

Selected Major Therapies

Chemotherapy	➡	Limited results; severe side effects
Radiation	➡	Limited results; severe side effects
Immunotherapies	➡	<20% effective rate; ultra-expensive
Canine Therapies	➡	~2 targeted drugs; limited results

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So What's Next?

While DBX-31 suggests amazing potential,

we still need to de-risk/prove this research with greater statistical certainty.

The next phase of work WILL show,

with ~90% scientific accuracy,

whether DBX-31 translates to human patients!

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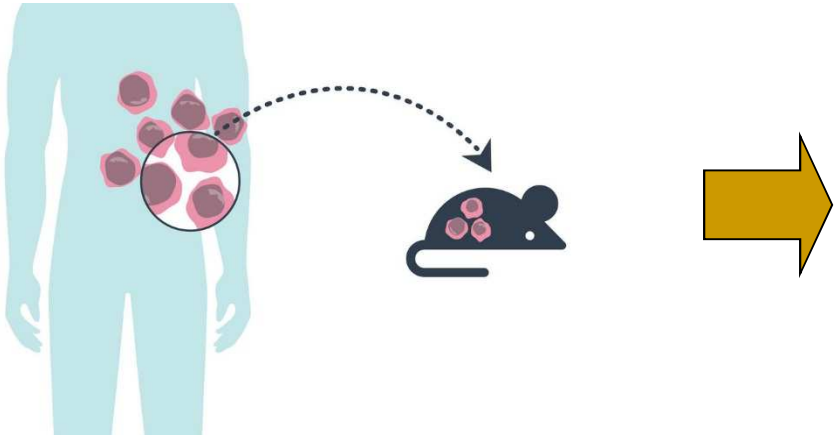
Development Plans

De-risk Using Highly Predictive Mice Models

Testing in Mice That Accurately Simulate Patient Responses

Patient Derived Xenografts (PDX) is an innovative platform technology able to accelerate the development of oncology drugs by predicting their clinical effectiveness with 90 – 100% accuracy



+90%

predictive of results in future human clinical trial

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Development Goals

Complete Preclinical Research

- Detailed Research Plan already developed in conjunction with Cornell University and Cornell University College of Veterinary Medicine (#1 Rated Program)
- Conduct *in vivo* research using novel highly predictive patient derived xenograft platform
- Dog/Canine trial at Cornell Veterinary Hospital
- Submit FDA/CVM drug application for dogs via development partnership/licensing deal

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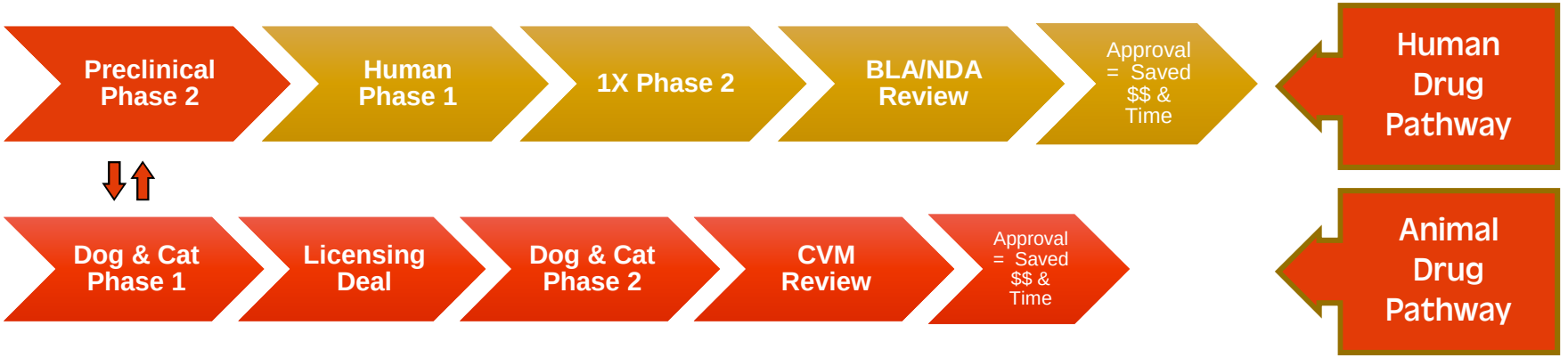
Development Timeline

Accelerated Approval = Lives, Time and Money



Standard Approval = More Steps, Cost, Delay

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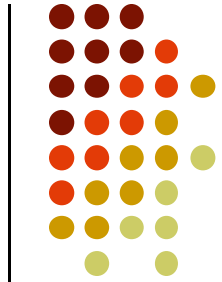
Focus on De-risking

Risk-Adjusted Net Present Value (rNPV)



Reduced ⇩ Risk = More ⇧ Attractive Investment

To <u>accurately</u> evaluate a new biotechnology, an entrepreneur must account for the future revenue from the final product, the cost and time needed to get the product to market, and the various risks faced along the way; this can be expressed in terms of risk-adjusted net present value (*rNPV).*

BioGenetic Ventures, Inc., Seattle, WA.
rNPV Model published by Nature Publishing Group

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rNPV: Before & After

De-risking Changes rNPV Dramatically

VALUE PROFILE - rNPV

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Risk-Added and Adjusted Values			YEAR 1	2	3
DEVELOPMENT STAGE			Preclinical	Preclinical	Phase 1
RISK MEDIATED			5%	5%	40%
RISK-ADDED COSTS	Annual Costs				
Patent Fees	$	15,000	300,000	300,000	37,500
Preclinical Research	$	500,000	10,000,000	10,000,000	-
Trials - Phase 1	$	1,255,100	-	-	3,137,750
Trials - Phase 2	$	4,890,000	-	-	
Trials - Phase 3	$	41,076,000	-	-	-
FDA Fees	$	1,300,000	-	-	-
Animal Studies 1 (1st year)	$	250,000	-	-	625,000
Animal Studies 2 (all years)	$	500,000	-	-	-
Animal Studies 3 (1st 2 years)	$	750,000	-	-	-
Manufacturing/Marketing		60%	-	-	-
Royalty Splits		0%	-	-	-
Other			-	-	-
Risk-Added Total Costs			10,300,000	10,300,000	3,800,250
PV of Risk-Added Total Costs			1,349,939,995	1,607,567,994	1,916,721,593
PV of Revenue			2,133,158,989	2,559,790,787	3,071,748,944
Risk Adjustment			5%	5%	40%
Risk Adjusted PV of Total Costs			67,497,000	80,378,400	766,688,637
Risk-Adjusted PV Revenue			106,657,949	127,989,539	1,228,699,578
Risk-Adjusted NPV			39,160,950	47,611,140	462,010,940

39,160,950

Risk Adjusted Net Present Value
Pre-Investment/Pre-Clinical Phase
(i.e. "BEFORE")

462,010,940

Risk Adjusted Net Present Value
Post-Investment/Assumes Pre-Clinical PDX Mouse Tests Succeed
(i.e. "AFTER")

The rNPV figures in this model are not proposed as valuation bases for or presented as a solicitation to buy or an offer to sell securities. They merely show the mathematical impact of reducing risk of project failure.

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Validating Sources

Supportive/Interested Entities

mava

Cornell University
College of Veterinary Medicine

NATIONAL CANCER INSTITUTE

Genentech
A Member of the Roche Group

bioCube
San Jose

Debiopharm Group
WE DEVELOP FOR PATIENTS

Johnson & Johnson INNOVATION | JLABS

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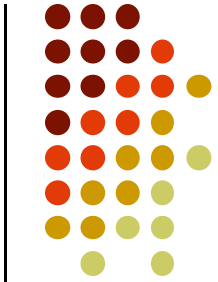
JOIN US. MAKE HISTORY.



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