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STRATEGY FOR THE LIFE SCIENCES

Business Plan for the Pre-revenue Company AbCure

PROJECT SNAPSHOT: BUSINESS PLAN

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What is AbCure

Abcure is a biopharma research services company with a novel platform for generation of high-potency/low toxicity biotherapeutics.

Value Proposition

AbCure has developed a design and construction platform for increasing the efficacy and safety of a revolutionary new class of anti-cancer biotherapeutics (antibody drug conjugates or ADCs). ADCs are made by attaching antibodies that bind to cancer cells to highly potent chemical drugs through a process called bioconjugation. Unlike conventional treatments that damage healthy tissues upon dose escalation, ADCs bind cancer-cell specific antigens and deliver a highly potent cytotoxic agent once inside the cell, making it possible to destroy cancer cells more effectively without causing toxicity in the rest of the body. ADCs represent an extremely promising class of anti-cancer drugs with an already large and rapidly growing clinical pipeline[1]. However, despite this exciting potential, several challenges including low chemotherapy drug potency, unstable linkers and low antigen selectivity have thus far limited the efficacy of many ADC candidates. AbCure's platform utilizes a novel genetic modification and enzymatic reaction process which overcomes many of these barriers to reliably produce antibody drug conjugates that are more effective and less toxic than those produced through currently available bioconjugation methodologies. AbCure's process generates more efficacious ADCs that are more likely to pass regulations and become available for clinical use.

The Science Behind the Platform:

AbCure's platform takes advantage of the enzyme Sortase A from the bacterium *Staphylococcus aureus*. This enzyme recognizes the LPXTG amino acid motif in a protein (in this case an antibody that has been engineered to contain LPXTG in a specific site), cleaves the threonine-glycine (T-G) bond, and attaches an oligoglycine-containing molecule (in this case a potent chemical drug that has been engineered to contain an oligoglycine motif).

To protect AbCure's novel platform, the company has filed 3 patents for its Sortase-A-enabled bioconjugation process.

[1] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4613712/

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Business Model

AbCure will function as a provider of bioconjugation services. AbCure's target market is segmented as follows:

PRIMARY MARKET
Companies developing drug bioconjugates
(most notably immunotherapeutics for cancer treatment)

SECONDARY MARKET
Companies developing diagnostic bioconjugates
(e.g. for in vivo imaging)

TERTIARY MARKET
Companies developing research-focused bioconjugates
(e.g. high through-put screening libraries)

The company's platform consists of 5 major service lines provided at 3 different scales:

Service Range:

DESIGN	OPTIMIZE	CONSTRUCT	EVALUATE	PRODUCE
• Custom design of linker and conjugation strategies	• Optimize antibody labeling sites • Optimize linkage chemistry	• Preperation • Conjugation • Purification • Lyophilisation	• Stability analysis • Bio-analyitical analysis • Pk studies in blood and tissue extracts • Formulation studies	• Custom design of linker and conjugation strategies • Packaged product

Service Scale:

mg batch

FOR R&D STUDIES

g batch

FOR PROOF OF CONCEPT OR PRECLINICAL STUDIES

kg batch

FOR cGMP MANUFACTURING

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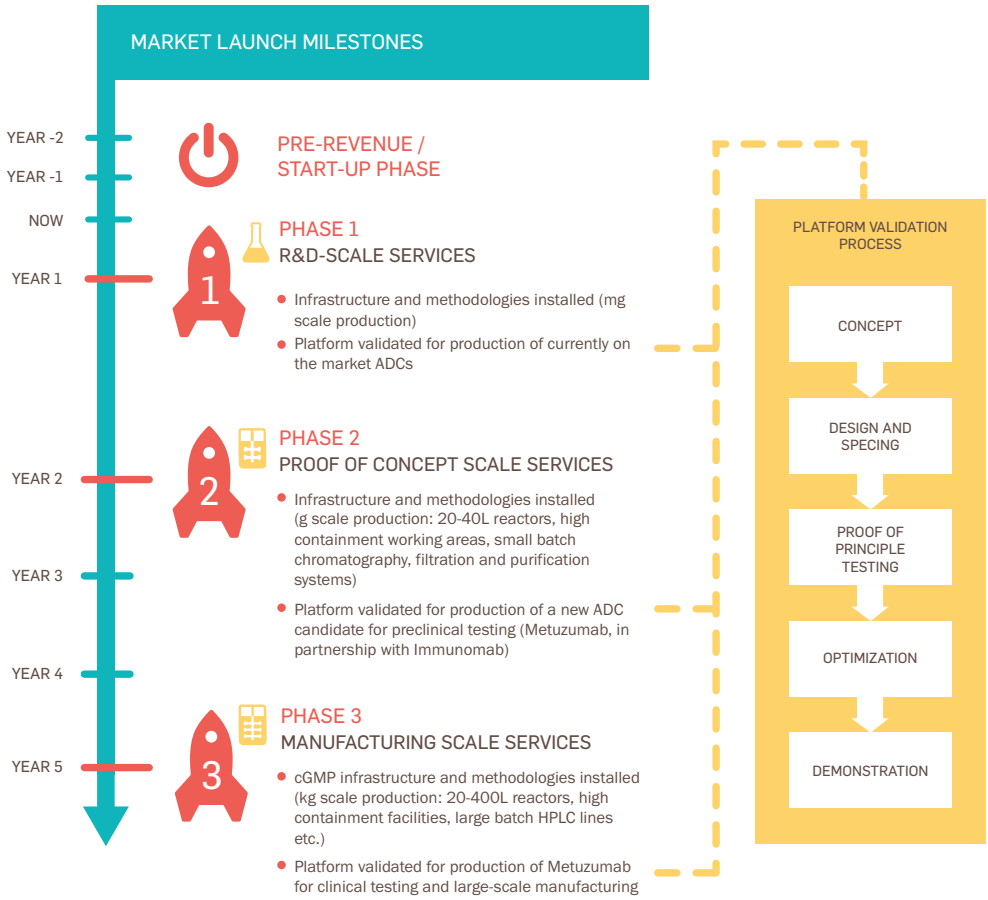
Market Readiness

AbCure has been in existence for 2 years and is in a pre-revenue stage of development. The company's commercialization plan consists of 3 phases for the launch of its R&D-scale platform (anticipated in the coming year), its proof-of-concept-scale platform (anticipated in 2 years) and its cGMP manufacturing-scale platform (anticipated in 5 years). For each phase, a scale-appropriate platform is installed and validated through a standardized pipeline.

Market Launch Plan



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Market Launch Plan (cont.)

Phase 1 launch is less than a year away: AbCure's R&D scale platform is in the final stages of validation. Over the course of the start-up phase (referred to as year -2 and year -1) an R&D-scale platform was installed and the platform was validated through a standard process. It was found that the platform can produce Abcertis and Kasdyla molecules (2 FDA-approved ADCs which are normally produced with traditional bioconjugation methodologies) with superior in vitro characteristics (better solubility, more homogeneous populations of particles with high drug to antibody load, and no adverse effect on antibody to antigen binding). Additionally, compared to traditionally-made Abcertis and Kasdyla, AbCure's platform produces ADCs with increased cell killing and decreased toxicity in animal models.

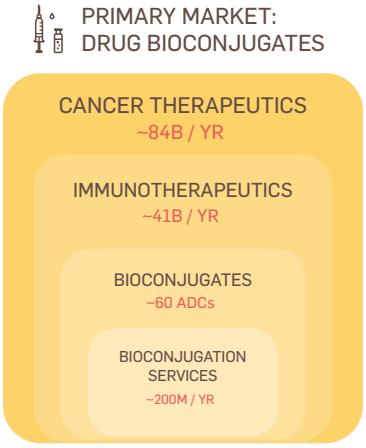
Phase 2 launch is 2 years away: Thus far, AbCure has acquired and installed a small facility for delivering proof-of-concept-scale services. To validate this platform, AbCure has partnered with the company Immunomab through a co-development agreement to produce Metuzumab, Immunomab's lead ADC candidate for the purposes of preclinical testing. To date, AbCure has supported Immunomab in designing Metuzumab based on Immunomab's finding that leukemia cancer cells are high expressers of CD37 antigen as compared to healthy cells. To evaluate humanized anti-CD37 monolconal antibodies as potential ADCs, one mAb was conjugated to the cytotoxic agent MMAE via AbCure's novel conjugation process. The molecule exhibited favourable stability and biochemical characteristics and according to Immunomab's pre-clinical studies, Metuzumab results in significant and sustained inhibition of malignant cell growth with no overt *in vivo* toxicity.

Market Research

AbCure's immediate customers are developers of anti-cancer immunotherapeutics. As the company initiates an expansion into other arenas (including but not limited to diagnostics and research), further intelligence will be gathered to strategically select and pursue favourable markets.

Market Demand

A detailed analysis of AbCure's primary market reveals that the overall market for cancer therapeutics stands at about $84.3 billion. Within cancer therapeutics, immunotherapy drugs have gained worldwide acceptance, because they are targeted only to cancer cells and generally demonstrate lower toxicity in healthy parts of the body. Today, cancer immunotherapy drugs have captured nearly 50% of the overall oncology drugs market, generating about $41.0 billion in 2014 alone. The antibody-drug-conjugate (ADC) is a novel therapeutic format within the immunotherapy sphere and has been cited as "having great potential to make a paradigm shift in cancer chemotherapy". There are currently 60 ADC molecules undergoing clinical evaluation in the United States but over the coming years this class of therapy is expected to become mainstream as design and manufacturing processes are optimized.



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Market Demand (cont.)

At the moment, almost all major research-based biopharmaceutical companies have a need for bioconjugation platforms, most for the production of ADCs specifically. In the last 5 years Kizer, KSG, Nerck, Danofi, Goche, Tayer and Milead have acquired small biotechs that focus on designing, optimizing and constructing conjugate biotherapeutics. Through market research interviews, R&D executives from each of these multi-nationals have expressed a strong interest in fostering strategic partnerships that provide access to novel approaches for enhancing antibody function or improving site-specific bioconjugation in biomolecule design and manufacturing.

The market for bioconjugation services in the United States for ADC molecules alone can be estimated at over $200M (in 2 years when AbCure is ready to go to market with its mid-scale manufacturing services). This estimate is calculated by examining the current pipeline of ADC molecules in development in the United States (~60, growing at an average of 40% per annum) and multiplying this number by the estimate cost of bioconjugation processes to bring a molecule from design all the way to manufacturing (~1.3M per molecule).

Competitive Positioning

AbCure is well-positioned to secure a large portion of the drug bioconjugate market with its superior technology, existing client relationships and demand-driven scope of services.

There are currently 3 market-dominant companies that provide custom bioconjugation services to the global R&D community: Absynthesis, Linovabiosciences and Abmosaic. All three of these companies specialize in developing research bioconjugates but also market to companies developing diagnostic and drug bioconjugates. AbCure's primary clients (large pharma) do not often engage the services of these (or other bioconjugation-focused companies). They utilize traditional (less than optimal) in-house bioconjugation methodologies or acquire companies (or license the IP of companies) with novel bioconjugation platforms of interest. Our primary research indicates that the key driver of this strategy is the lack of manufacturing capability from the part of the bioconjugation companies that compare to in-house standards or the lack of a service line dedicated solely to the efficient and effective transfer of tailored manufacturing protocols to the biopharma client. AbCure fills both these gaps in its envisioned business model.

Furthermore, AbCure has conducted extensive primary interviews with R&D executives at 7 of its large biopharma target clients and 5 have demonstrated a strong interest in developing a long-standing service relationship with the company. AbCure estimates that among these 5 target clients, there are ~20 bioconjugate compounds/year that could be optimized and further developed with the use of its novel platform.

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Marketing and Sales

AbCure has put in place key success factors for effective marketing and sale of its services. These include:

Focused client identification and targeting:

- AbCure has developed a tiered list of clients to prioritize sales and marketing efforts in the first 3 years.

TIER 1 — Tier 1 target clients consist of 7 large biopharmaceutical companies with a significant drug bioconjugate R&D presence.

TIER 2 — Tier 2 clients consist of approximately 30 small-medium sized biotechs in North America focused on the development of anti-cancer immunotherapy with a pipeline of at least one ADC candidate as well as 20 diagnostic companies developing conjugate molecules for identification of disease.

TIER 3 — Tier 3 clients consist of ~300 leading academic labs in North America with the need for high through-put biological screening libraries.

Dedicated sales staff:

- AbCure has in place 3 full time staff with a primary business development function consisting of a chief scientist and 2 scientific liaisons.

Existing trust with tier 1 clients:

- AbCure's Chief Scientist is the former global R&D head for Kizer's biologics platform and the 2 scientific liaisons are former product managers at Glycobio, a bioconjugation technology company that was recently acquired by KSG.

Demand pull:

- Abcure's tier 1 clientele have all been engaged to varying degrees in the development of the platform at an early stage in order to ensure AbCure's services and technology are directly addressing their R&D needs.

Access to additional motivated clients/partners:

- AbCure has developed a list of 25 ADC molecules that have failed regulatory approval at a late stage of development in the last 5 years. As AbCure's platform has a strong possibility of mitigating some of the flaws in chemistry and efficacy that led to the failure of these molecules, it is currently in discussion with the developer companies to negotiate a service contract or licensing agreement to reinvigorate these development pipelines.

Strategic print and digital marketing narratives:

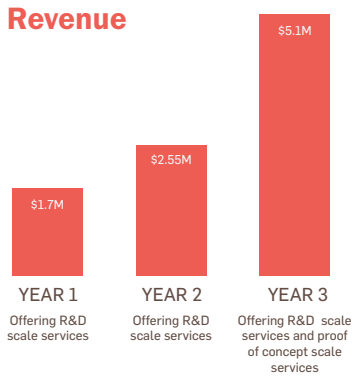
- AbCure is developing a comprehensive digital and print marketing package in collaboration with a scientific communications firm including a website, case studies, informational brochures and videos for the purpose of client education and to support sales.

Sound pricing strategy:

- AbCure has conducted primary consultations with ~ 10 key stakeholders from each of its client target groups to assess price tolerance for its services and has devised a pricing strategy that is in accordance with these.

Informed business development goals:

- AbCure has established sales goals for the first 3 years of its operations based on the state of its relationships and conversations with critical prospects from its 3 client target groups.



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Operations

Executive Management

Marsha L. Snare, CEO

- Founder & CEO of Fiomora, 700-person integrated research CRO in Germany, sold to Pharmaceutical Product Development Inc. with attractive returns
- CEO of Galenea, Boston biotech started from MIT with funding from BioVC Ventures
- Founder, President of Phia, sold to Rieman's
- Co-CEO of Genta, publicly-traded oncology company with $1.7 billion in revenues
- Began career at McKinsey & Company
- MBA from Stanford University
- B.S. from Massachusetts Institute of Technology

Rory Ellis, Chief Scientist

- Global head of R&D for Biologics at Kizer
- Vice President and Head of Clinical Development at Certa Pharma
- Vice President, Research, Jonhson Comprehensive Cancer Center
- Medical Director, Product Development-Oncology at Genetech (a Member of the Goche Group)
- Director, California BioSystems Institute
- M.D. and PhD from University of Washington School of Medicine
- Bachelor of Science degree with Honors in Biological Sciences from Stanford University

Advisory Board

George Crollo, Chairman of the Board

George has over 35 years of experience in the pharmaceutical industry, with an emphasis on biologics. Most recently, he served, first as President and Chief Operating Officer, and later as deputy CEO, at Danofi. From 1994 to 1998, he helped establish and also served as President and CEO of CompiBio, a joint venture between Nerck & Co. and CompiBio Lenark. Mr. Crollo has served as President of the North American International Association of Biologics Manufacturers (NAIABM) and as a member of the World Health Organization's Strategic Advisory Group of Experts. He received a Master's degree from the Institut d'Etudes Politiques de Paris and an MBA from the Richard Ivey School of Business Administration at the University of Western Ontario.

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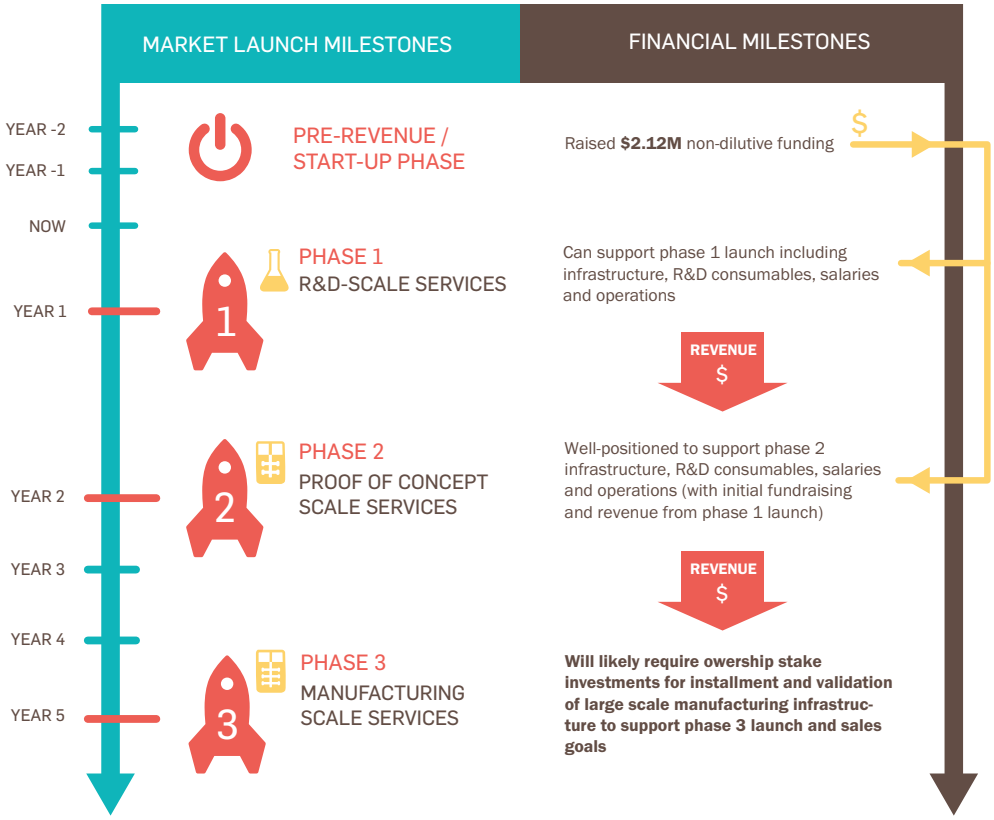
Infrastructure Assets

Small-scale, high containment GMP compliant working lab:

- Bioreactors (20-40L)
- Continuous chromatography system
- Filtration system: Multiple TFF units for MF and UF/DF and virus removal
- Filter dryers fit for the production of g-scale batches

Financials



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Financials (cont.)

Non-Dilutive Funding Raised in Start-up Phase:

ROUND	FINANCER	AMOUNT	PURPOSE	TYPE
ANGEL	Private investors	750,000	Infrastructure and salaries	Non-dilutive grant
SEED	SBIR, US Government	800,000	Infrastructure, consumables, salaries	Non-dilutive grant
SEED	IRAP, Government of Canada	75,000	Infrastructure, consumables, salaries	Non-dilutive grant
SEED	OICR, Government of Ontario	500,000	Infrastructure, consumables, salaries	Non-dilutive grant
TOTAL				$2,125,000

Projected profits post-launch are based on business development goals and history of spending in Years 2 and 1:

	PROJECTED SALES (M)	PROJECTED EXPENSES (M)	NET GAINS OR LOSSES (M)
YEAR 1	$1.7	$0.743	$0.957
YEAR 2	$2.55	$1.1	$1.45
YEAR 3	$5.1	$1.6	$3.5

AbCure is open to ownership stake investments based on a reasonable pre-revenue evaluation. These funds will be primarily employed toward the installment and validation of large-scale manufacturing infrastructure to support the company's phase 3 launch and sales goals.

Spending in Start-up Phase:

EXPENSES	YEAR 2	YEAR 1
START-UP COSTS		
LICENSE	$1,200	
EQUIPMENT	$250,000	$150,000
FURNITURE	$7,000	
LEGAL FEES	$6,000	
CERTIFICATIONS	$20,000	
MARKETING MATERIAL	$15,000	
RECURRING COSTS		
SALARIES	$363,000	$398,000
CONSUMABLES	$111,000	$95,000
GROSS LEASE	$38,000	$45,000
OTHER	$35,000	$41,000
YEARLY TOTAL	$845,200	$729,000
TOTAL		$1,574,200