

**Corporate Presentation September 2015** 



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Those factors include risks and uncertainties relating to DARA's ability to timely commercialize and generate revenues or profits from Soltamox®, Gelclair®, Oravig® or other products, DARA's ability to achieve the desired results from the agreements with Mission and Alamo, FDA and other regulatory risks relating to DARA's ability to market Soltamox, Gelclair, Oravig or other products in the United States or elsewhere, DARA's ability to in-license and/or partner products, the current regulatory environment in which DARA sells its products, the market acceptance of those products, DARA's ability to develop KRN5500 into an FDA-approved commercial product, dependence on partners, successful performance under collaborative and other commercial agreements, competition, the strength of DARA's intellectual property and the intellectual property of others, the potential delisting of DARA's common stock from the NASDAQ Capital Market, the ability to consummate the merger with Midatech PLC, and other risk factors identified in the documents DARA has filed, or will file, with the Securities and Exchange Commission ("SEC"). Copies of DARA's filings with the SEC may be obtained from the SEC Internet site at <a href="http://www.sec.gov">http://www.sec.gov</a>. DARA expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in DARA's expectations with regard thereto or any change in events, conditions, or circumstances on which any such statements are based. DARA BioSciences and the DARA logo are trademarks of DARA BioSciences, Inc.

# **Corporate Overview**



DARA BioSciences, Inc. is a specialty pharmaceutical company focused on the commercialization of oncology supportive care and treatment pharmaceutical products.

- NASDAQ:DARA
- Headquarters in Raleigh, NC
- National sales force of 20 representatives
- Continued strong revenue growth in 2015
- Pending M&A with Midatech (AIM:MTPH)

# Marketed Products (1)











# **Future Opportunities**

Phase 2b-ready drug with "Fast-Track" status for the treatment of CCIPN<sup>(2)</sup> and two FDA Orphan designations for CCIPN and multiple myeloma

# **KRN5500**

Licensing discussions for additional supportive care products:









l) Including two products through shared sales force agreement with Mission Pharmacal; Oravig is FDA-approved, DARA plans to launch in 2H 2015



# Pending M&A - Midatech Pharma (AIM:MTPH)

Midatech Pharma is a UK-based nano-medicine development company with novel technology and a range of compounds in development targeting rare cancers.

- DARA will be the US Commercial Organization, continuing to sell its portfolio of products in oncology supportive care.
- Larger, combined company to maximize potential of existing portfolio products and future pipeline opportunities
- Continued efforts to license / acquire additional synergistic products
- Midatech will list on Nasdaq via ADR's
- Transaction is expected to close in Q4'15

#### DARA Bi()Sciences

# **New Product Acquisition - Oravig**

# Oravig is FDA approved and a highly synergistic and high potential product in oncology supportive care and broader markets

- DARA has exclusive US license to Oravig, for Oropharyngeal Candidiasis (oral thrush)
  - Potential to pursue regulatory approval in Canada
  - Synergistic with the current DARA supportive care portfolio
  - Broadens existing relationship with Mission Pharmacal to promote Oravig with its primary care sales force
- Significant market potential with over 3 million prescriptions written annually
  - Oravig fits ideally into DARA's supportive care portfolio and provides a unique "Oral Oncology Supportive Care Franchise" when combined with Gelclair and Aquoral.
- Oravig provides DARA a new partnership with Onxeo, a well established international oncology supportive care company

# Why Oncology Supportive Care?



# What is oncology supportive care?

"Care given to support the quality of life in cancer patients. The goal is to **prevent** or **treat** as early as possible the symptoms of the disease, **side-effects** caused by treatment and psychological, social and spiritual problems caused by the disease."



Large, Untapped & Growing Market	<ul> <li>Virtually all cancer treated patients involved</li> <li>Improved therapeutics increasing the demand for supportive care products</li> </ul>	
Significant Commercial	<ul> <li>Each product addresses unmet medical need</li> <li>Competitive products non-existent or sub-optimal</li> </ul>	
Opportunity	<ul> <li>Growth potential</li> <li>Expand into other supportive care areas/comprehensive portfolio</li> </ul>	
Unique Positioning	<ul> <li>Establish leadership position in the specialty pharma market</li> <li>We believe there is no comparable company with equivalent breadth of product portfolio</li> </ul>	
<b>Product Synergies</b>	Portfolio concept: one patient served by multiple DARA products	

# **Product Portfolio**

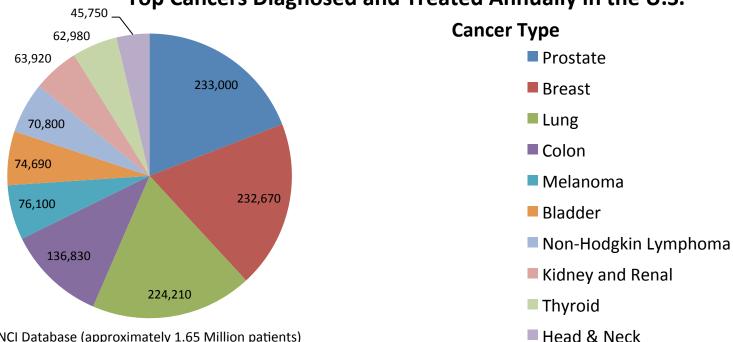


	Product	Status	Licensing Partner
In-Licensed Commercial Products	Gelclair®  Hyaluronic acid oral rinse gel Oral mucositis	Marketed	Helsinn
	Oravig™  Indicated for the local treatment of OPC in adults  OPC in adults	Approved NDA	Onxeo
	Soltamox®  Oral liquid tamoxifen citrate breast cancer	Marketed	Perrigo (Rosemont)
Co-Promoted Products	Ferralet® 90  Dual Iron delivery anemia supplement	Marketed	Mission Pharmacal
	Aquoral®  Oral spray treatment dry mouth	Marketed	Mission Pharmacal
Clinical Development	KRN5500® Non-opioid NCE painful refractory CCIPN & multiple myeloma	Phase 2b	Kirin
Active Licensing Efforts	Additional supportive care products	In Discussions	Various









\*SEER NCI Database (approximately 1.65 Million patients)

Common Types of Conser	Common Side Effects (> 200/)	
Common Types of Cancer	Common Side Effects (>30%)	DARA Products
Prostate	Fatigue	Ferralet 90
Breast (Female)	OM, Dry Mouth, Thrush, Fatigue	Gelclair, Aquoral, Oravig, Ferralet 90, Soltamox
Lung and Bronchus	OM, Dry Mouth, Thrush	Gelclair, Aquoral, Oravig
Colon and Rectum	OM, Dry Mouth, Fatigue,	Gelclair, Aquoral, Ferralet 90
Melanoma	Fatigue	Ferralet 90
Bladder	OM, Dry Mouth	Gelclair, Aquoral
Non-Hodgkin Lymphoma	OM, Dry Mouth, Thrush, Fatigue	Gelclair, Aquoral, Oravig, Ferralet 90
Kidney and Renal Pelvis	OM, Dry Mouth	Gelclair, Aquoral
Thyroid	OM, Dry Mouth, Thrush, Fatigue	Gelclair, Aquoral, Oravig, Ferralet 90
Head & Neck	OM, Dry Mouth, Thrush, Fatigue	Gelclair, Aquoral, Oravig, Ferralet 90

# **Management Team**



#### **Christopher Clement – President and Chief Executive Officer**

• Held a number of senior management positions with several pharmaceutical companies, including Savient Pharmaceuticals, Inc. (Nasdaq:SVNT), Ares-Serono Group, Epicyte Pharma, Searle Pharmaceutical LLC, Merck & Co. Inc. (NYSE:MRK), and Novartis AG (SWX:NOVN).

#### David J. Drutz, MD - Executive Chairman & Chief Medical Officer

• Held a number of senior management positions with several pharmaceutical companies, including Tranzyme, Inc. (Nasdaq:TZYM), Inspire Pharmaceuticals, Inc., Daiichi Pharmaceutical Co., Limited (TSE:4568), and Smith Kline & French Laboratories.

#### **David Tousley – Chief Financial Officer**

 Held a number of senior management positions with several pharmaceutical and biotechnology companies, including PediatRX, Inc., airPharma, LLC, PediaMed Pharmaceuticals, Inc., AVAX Technologies, Inc., and Pasteur Merieux Connaught (now Sanofi Pasteur, a subsidiary of Sanofi (ENXTPA:SAN)).

#### John Petrolino – General Counsel & Chief Compliance Officer

• Held a number of positions of increasing responsibility in the Legal departments of publicly traded pharmaceutical and biotechnology companies, including most recently Deputy General Counsel and Chief Compliance Officer at Savient Pharmaceuticals, Inc.

#### Mary Kay Delmedico, PhD – Vice President of Scientific & Regulatory Affairs

Held senior project leadership roles in support of scientific, clinical, regulatory, and strategic objectives, including infectious diseases (Trimeris, Inc.),
diabetes and oncology supportive care (DARA BioSciences). Participated in the design and development of products from early discovery through
clinical development and commercialization.

#### David Benharris – Sr. Vice President of Commercial Operations and Business Development

• Held a number of management positions with several pharmaceutical and biotechnology companies, including Genentech/Roche Holdings AG (SWX:ROG), Savient Pharmaceuticals (NASDAQ:SVNT), Insmed (Nasdaq:INSM), and EMD Serono/Merck KGaA.

#### Len Tenzer - Vice President, Sales and Marketing

• Former Vice President of Sales and Marketing at Patterson Medical (PDCO). Increased North American revenue from \$160 million to \$275 million. Led the commercial development and successful launch of Oxytrol® at Watson Laboratories. As Vice president of Sales at Pharmacia, launched Celebrex® and Detrol LA®, and coordinated one of the largest sales force merger integrations in the pharmaceutical industry. Directed the global commercial development of Arthrotec®, Celebrex®, and Bextra® as the Executive Director of Searle's arthritis and pain franchise.

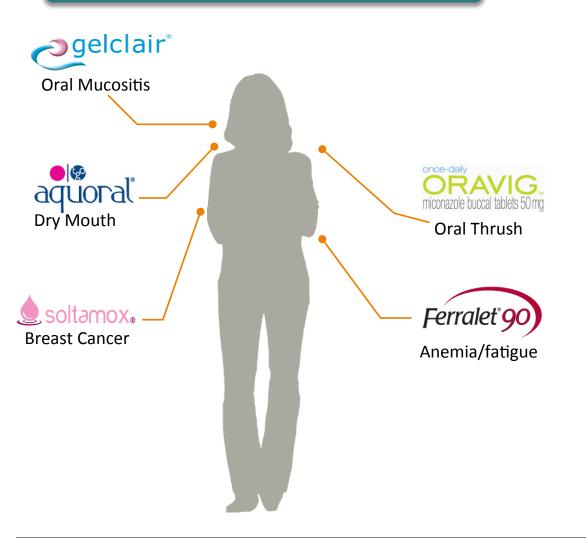
Over 100 years of collective expertise in clinical development, operations, sales & marketing, strategic planning, regulatory affairs and technical operations.



# **Synergistic Product Portfolio**



# **Example: Breast Cancer**



# Multiple discussion points within hospital/office setting:

- Receptionist/Office Manager
- Oncologists
- Nurses
- PAs/NPs
- Radiologists

DARA leverages its portfolio of oncology supportive care products to treat an array of oncology related indications in the same patient

### **Sales Force Metrics**



# Sales team driving revenue growth with highly targeted focus

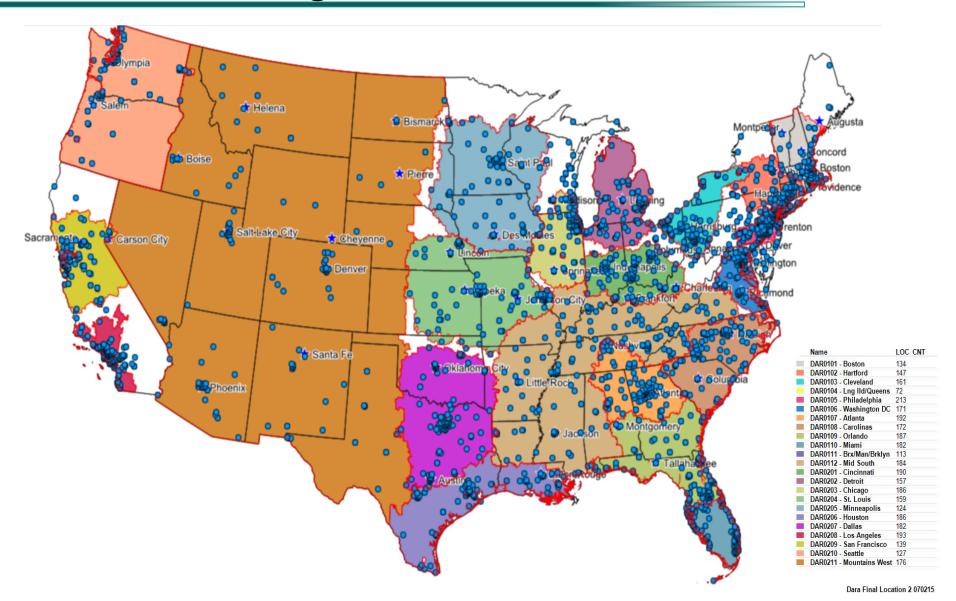
- Top deciled oncology prescribers (80% of volume)
- Excellent access to target offices
- Portfolio story resonates well
- Sales efforts supplemented with non-personal programs
- Personal involvement / commitment
- Sales reps are all "proven" performers

# Partnership with ALAMO ideally complements DARA:

- Full service provider
  - Infrastructure / SFA
  - Time / cost efficient
- Success with similar specialty companies
  - "White Space" Programs initiated in June 2015
- Potential new supportive care product opportunities

# **National Coverage**



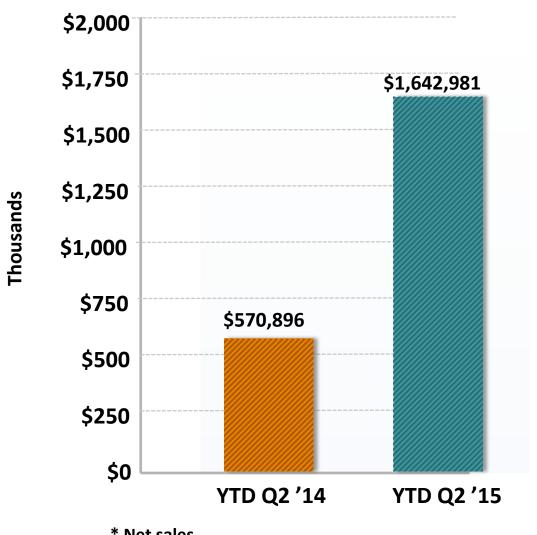


Uncategorized

# **Record Sales Growth\***



### Net Revenues increased 188% y/y



<sup>\*</sup> Net sales

## **Recent Sales Trends**



#### Continuing strong momentum and progress realized by sales force

- Positive trend led by Gelclair® demand
- Gelclair<sup>®</sup> prescription leader in U.S. retail gel barrier market
- Strong relationships with key customers
- Positive feedback and commitment to usage

#### Increased formulary/specialty pharmacy approvals for Gelclair® and Soltamox®

- Gelclair approved for preferred formulary position by both national payers and leading cancer institutions
- Soltamox granted improved formulary status at 3 major Medicare Part D Plans

#### Continued success of "No Hassles" retail program

Proactively capture more demand for Gelclair and Soltamox

# Growth achieved across other products in portfolio which are positive indicators of the synergistic benefits of our portfolio

Achieved sequential growth of both Ferralet and Aquoral in the Oncology Market

# **Continued positive momentum and results**

# **Gelclair®**





Gelclair® is a patented, oral bioadherent gel (mouthwash) indicated for management and relief of painful symptoms of oral mucositis, a significant side effect for patients receiving chemotherapy or radiotherapy.



Indication	Oral mucositis/stomatitis (side effect of cancer therapies)
Delivery Method	Gel packet is diluted in water to rinse the mouth & throat
Competitive Advantage	<ul> <li>Convenient / easy to use</li> <li>Hyaluronic acid based – aids mucosal hydration; may aid healing</li> <li>Improvement in quality of life (eat and drink normally/speech/sleep)</li> <li>Contains no ethanol</li> </ul>
Territory Rights	• U.S.
Market Size	• 80,000 patients <sup>(1)</sup>

40% to 70% of individuals treated with standard chemotherapy can have oral mucositis. (\*80% of people with cancer of the head/neck who receive radiotherapy develop oral mucositis.)

# Oravig™





Oravig is the first and only orally-dissolving, buccal tablet for oral thrush. Oravig provides immediate and sustained release of miconazole, has proven efficacy, minimal systemic absorption and has convenient once-daily dosing to treat oral thrush, a common side effect in cancer patients



Indication	ORAVIG is indicated for the local treatment of oropharyngeal candidiasis (OPC) in adults
Delivery Method	ORAVIG (miconazole) buccal tablets are applied topically to the gum once daily and release miconazole as the buccal tablet gradually dissolves
Competitive Advantage	<ul> <li>Once-daily, local treatment</li> <li>Immediate and sustained release at the site of infection</li> <li>No added flavoring or sweetener</li> <li>Flavorless and odorless</li> <li>Reduces the treatment burden for patients on a multidrug regimen</li> <li>Does not interrupt eating or drinking</li> </ul>
Territory Rights	U.S. with the right to pursue regulatory approval in Canada
Market Size	3,000,000 total cases of OPC treated annually (1)

# **Soltamox®**





# Soltamox® is the <u>only patented</u>, oral liquid formulation of tamoxifen in the U.S. and is an important option for breast cancer patients with difficulty adhering to tablet therapy.



Indication	<ul> <li>Treatment of metastatic breast cancer</li> <li>Adjuvant treatment of breast cancer</li> <li>Reduce the risk of invasive breast cancer in women with DCIS</li> <li>Reduce the risk of breast cancer incidence in high risk women</li> </ul>
<b>Delivery Method</b>	Oral liquid formulation (usually administered 1x daily up to 5 years)
Competitive Advantage	<ul> <li>Only FDA-approved liquid formulation of tamoxifen citrate</li> <li>Alternative to patients that prefer or need a dosing alternative</li> </ul>
Territory Rights	• U.S.
Market Size	• 2.6 Million patients (US)

#### Breast cancer is the 2<sup>nd</sup> leading cause of cancer mortality in women with ~230,000 new diagnosis each year.

- Tamoxifen is a widely used preventive treatment for "high risk" patients.
- Stable market, modest growth expected.
- According to the American Society of Clinical Oncology,<sup>(1)</sup> women diagnosed with hormone receptor-positive breast cancer should be offered adjuvant endocrine therapy with tamoxifen for a duration of up to 10 rather than the label-recommended treatment of 5 years.

Important safety information, Boxed Warning & full prescribing information available at <a href="https://www.soltamox.com">www.soltamox.com</a>

# **Ferralet**®





# Ferralet® is a patented iron supplement indicated for patients with iron-deficiency anemia (insufficient healthy red-blood cells)



Indication	IDA (iron deficiency anemia)
Delivery Method	Once-daily pill
Competitive Advantage	<ul> <li>Unique dual-iron formulation (immediate/prolonged absorption)</li> <li>Contains the stool softener docusate sodium</li> <li>Also contains Vitamin B12 and folic acid (helps prevent megaloblastic anemia) and Vitamin C (aids in absorption)</li> </ul>
Territory Rights	• U.S.
Market Size (incidence)	• 500,000 – 1,400,000 newly-diagnosed patients / year (1)

• 30 – 90% of cancer patients have anemia,(1) due to many factors

# **Aquoral**®





Aquoral® is an artificial saliva substitute indicated to provide relief from temporary and chronic xerostomia (dry mouth) which may be a result of disease such as Sjogren's Syndrome, oral inflammation, medication, chemotherapy or radiation, stress, or aging.



Indications	Xerostomia (dry mouth, due to reduced or absent saliva flow)
<b>Delivery Method</b>	Spray (canister)
Competitive Advantage	<ul> <li>Easy to administer</li> <li>No pre-mixing required</li> <li>Duration of action (each application lasts up to 4 hours – other treatments may need to be given 10X per day)</li> </ul>
Territory Rights	• U.S.
Market Size (incidence)	<ul> <li>240,000 newly-diagnosed patients will have pre-existing xerostomia <sup>(1)</sup></li> <li>52,000 patients are diagnosed with head and neck cancer each year. <sup>(2)</sup></li> </ul>

- ~15% of the general population experiences xerostomia (1)
- Nearly all patients treated for head and neck cancer experience xerostomia & 70 90% will continue > 2 years after treatment (3)
- More than 400 commonly used drugs cause xerostomia (4)
  - (1) Liu et al., Oral Medicine, 2012; Vol. 114: pp. 52 60.
  - (2) NCI Facts and Figures, www.cancer.gov
  - (3) Jensen, et al., Support Care Cancer, 2010; Vol. 18: pp. 1061 1079.
  - (4) Supportive Care Cancer 2015; vol.23: pp. 881 888.

# **Expansion Opportunities**



Full portfolio offering of synergistic supportive care products is a competitive differentiator

DARA is focused on adding additional supportive care products to the portfolio in the near-term

- Immediately monetized
- Acquire/License
- Strategic partnerships

Ideal partner to handle niche, supportive care products

Acquiring additional supportive care portfolio products is a high priority for DARA



# **KRN5500: A Novel Phase 2 Drug**



# DARA's clinical development compound targets painful CCIPN\*

- Area of significant unmet medical need
  - Existing therapies are marginally effective
- Impressive Phase 2a clinical results
- "Fast track" status from FDA | Orphan designation granted February 2014 for CCIPN

# Why is KRN5500 so exciting?

#### Highlights

- Non-opioid
- Unmet medical need
- Statistically significant results in a small clinical trial of refractory patients (vs. placebo)
- Prolonged duration of action

#### Clinical Trial

- 24% reduction of pain (p=0.03)
- 29.5% median maximal reduction (p=0.02)
- 83% clinically meaningful (>20%) improvement (p=0.04)
- No drug related SAE's; nausea/vomiting common but antiemesis therapy not optimized

# **KRN5500 Phase 2a Primary Endpoint**



#### KRN5500 reduces median target pain intensity 24%: placebo 0% (p=0.03)



- Primary Endpoint = median Clinic NRS scores 1 week after final dose
- KRN5500 24%; Placebo 0%
- p=0.03 (Wilcoxon Rank Sum Test)

## **KRN5500 Recent Advances**

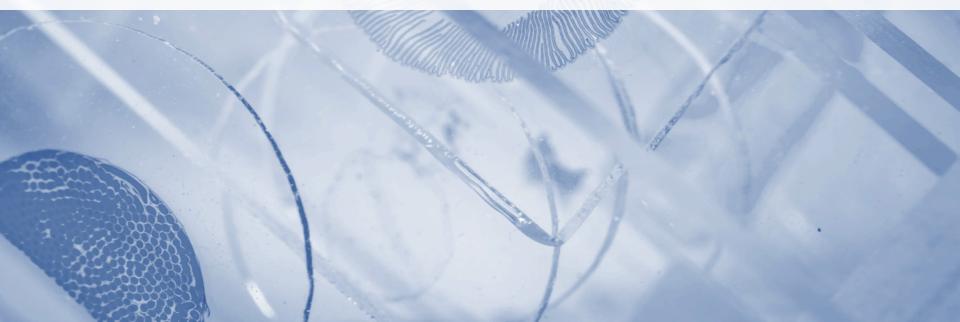


# **July 2015**

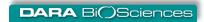
- New formulation patent issued
  - Simplifies IV administration to a single step
  - Extends IP protection to 2033
- Formal agreement with FDA for full CCIPN development program, beginning with Phase 2b confirmatory trial
  - 3 doses + placebo
  - ~80 patients
  - ~12 cancer centers
  - ~18 months to top-line data
- Strategy continues to be pursuit of development partners



Capitalization Table







Cash	\$7.0 million
	None
Debt	None
Common Outstanding Shares (1)	19.9 million
Warrants (weighted average price of \$2.41)	17.1 million
Options (weighted average price of \$2.08) (2)	2.7 million
Fully Diluted Shares Outstanding	39.7 million

Source: Company's Internal Data

<sup>&</sup>lt;sup>(1)</sup>Includes Series A, B-2 and C-1 convertible preferred stock on as-converted basis

<sup>(2)</sup> Excludes 3.1 million shares reserved for issuance under the 2008 Equity Incentive Plan

# **Investment Summary**



# **Compelling Investment Opportunity | Near-Term Value Creation**

- Exciting novel new product acquisition in Oravig that will be accretive to sales revenues in 2015
- Unique strategic positioning with a portfolio of synergistic oncology supportive care products
- Positive and ongoing sales momentum
- Novel phase 2b-ready drug with multiple orphan designations that address a significant unmet need
- Pending M&A with Midatech Pharma
- Significant valuation upside given high growth potential

