



Fennec Pharmaceuticals Inc. is a speciality pharmaceutical company focused on the development of PEDMARK™ (a unique formulation of sodium thiosulfate) for the prevention of platinum-induced ototoxicity in pediatric patients. Cisplatin, a widely used platinum based chemotherapy agent, can cause irreversible and permanent hearing loss in children. Fennec has completed two pediatric Phase III studies to evaluate the reduction in ototoxicity and impact on survival. PEDMARK™ is an investigational new drug and has not yet been approved by the U.S. Food and Drug Administration (FDA) or any regulatory authority.

## INVESTMENT HIGHLIGHTS

### US Orphan Drug Designation (7.5 years market exclusivity).

- Potential for 10 years of European market exclusivity for pediatric use.

**Significant unmet medical need** with no approved treatment on market or in development.

**Completed enrollment** of two Phase 3 trials.

**Proof of concept** COG Phase 3 trial achieved primary endpoint for hearing

- Achieved primary efficacy endpoint of hearing loss protection,  $p=0.004$ .

**SIOPEL 6 Phase 3** trial showed that the addition of sodium thiosulfate significantly reduces the incidence of cisplatin-induced hearing loss without any evidence of tumor protection.

- Among the 101 evaluable patients, hearing loss occurred in 29/46=63% under Cisplatin Arm and in 18/55=33% under Cis+STS Arm;  $p=0.002$ .

STS safe to treat SR-HB with six cycles cisplatin monotherapy with the delayed addition of STS (ASCO/ New England Journal Medicine 2018).

**Breakthrough Therapy and Fast Track** granted in March 2018.

**NDA submission process initiated for the prevention of ototoxicity in pts. with localized, non-metastatic, solid tumors.**

## ABOUT US

NASDAQ .....	<b>FENC</b>
TSX .....	<b>FRX</b>
Recent Market Price .....	<b>USD \$5.83</b>
Shares Outstanding .....	<b>19.9M</b>
Cash* .....	<b>USD \$22.8M</b>
Cash Runway .....	<b>2H 2020</b>
Debt** .....	<b>\$0</b>

\* September 30, 2018  
\*\* With 12.5M facility to be funded at the Company's option upon NDA approval

## INSTITUTIONAL OWNERSHIP

Southpoint Capital - 20%  
Leadiant Bio (Sigma Tau) – 16%  
683 Capital – 6%  
venbio Select Advisor - 6%

Opaleye Management - 5%  
Eventide Funds - 4%

## MARKET OPPORTUNITY

In the U.S. and Europe it is estimated that over 10,000 children are diagnosed each year with cancers that may receive platinum based chemotherapy. These tumors have generally good prognosis with survival rates of greater than 80%, further emphasizing the importance of quality of life after treatment is completed. The incidence of hearing loss in these children is approximately 60%, with many requiring lifelong hearing aids and technically difficult and sub-optimal cochlear (inner ear) implants. Infants and young children at critical stages of development with even mild hearing loss lack speech language development and literacy, while older children and adolescents

lack social-emotional development and educational achievement. There is currently no established preventive agent for ototoxicity on the market.

STS has been studied by cooperative groups in two Phase 3 clinical studies of survival and reduction of ototoxicity, The Clinical Oncology Group Protocol ACCL0431 and SIOPEL 6. Both studies are closed to recruitment. The COG ACCL0431 protocol enrolled one of five childhood cancers typically treated with intensive cisplatin therapy for localized and disseminated disease, including newly diagnosed hepatoblastoma, germ cell tumor, osteosarcoma, neuroblastoma, and medulloblastoma. SIOPEL 6 enrolled only hepatoblastoma patients with localized tumors.

## BOARD OF DIRECTORS

**DR. KHALID ISLAM** | *Chairman of Board*  
Chairman & CEO at Gentium S.p.A. Sold to Jazz Pharma for \$1 billion.

**DR. MARCO BRUGHERA** | *Director, CEO & Global Head of Leadiant BioSciences Ltd.* Previously successfully outlicensed Defibrotide US rights to Jazz Pharma to Baxalta for \$1 billion.

**ROSTY RAYKOV** | *CEO & Director*

**ADRIAN HAIGH** | *Director.* Currently SVP & GM at PTC Therapeutics. Previously COO at Gentium S.p.A. Sold to Jazz Pharma for \$1 billion.

**CHRIS RALLIS** | *Director.* Previously President & COO of Triangle Pharmaceuticals. Sold to Gilead for \$500 million.

## CONTACT US

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