

# Q BioMed Inc

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## Q BioMed to apply for Orphan Drug status with FDA, European regulators for its pediatric autism drug

Q BioMed Inc (OTCMKTS:QBIO) announced Tuesday it plans to apply for Orphan Drug status with US and European regulators for its pediatric autism drug candidate QBM-001.

QBM-001 aims to treat toddlers with pediatric nonverbal autism who suffer from nonverbal or minimally verbal capabilities (PMVA). The company says there is no effective treatment available to treat an estimated 250,000 children born each year worldwide (20,000 in the US) with the affliction.

Q BioMed said that this month it will ask the US Food and Drug Administration and the European Medicines Agency for Orphan designation, which is given to drugs that treat less than 200,000 patients per year in the US. QBM-001 should be able to treat 15,000 US children, the company said.

READ: Q BioMed uncovers first biomarkers for pediatric nonverbal autism Orphan Drug designation offers clinical development benefits including tax credits and eligibility for seven years of market exclusivity in the US and 10 years in Europe.

The company said its application to the FDA and EMA will be based on its recent breakthrough discovery of two biomarkers that identifies PMVA. The company's study examined 1,953 autistic biomarkers.

"Q BioMed is committed to delivering relief to the children and families that are impacted by this condition," said CEO Denis Corin. "The emotional strain of never talking with one's child can be severe, and the direct financial costs over a lifetime are estimated to be \$4.5 million per family."

In the meantime, the New York-based company's second phase of QBM-001's formulation is expected to be finalized in August 2019.

At that time, Q BioMed said it will request a pre-investigational new drug meeting with the FDA and similar discussions with Europe's EMA. Based on regulatory guidance, Q BioMed anticipates filing its new drug meeting submissions, including its current clinical trial design, in December.

And clinical trials may commence as early as the first quarter of 2020, the company said.

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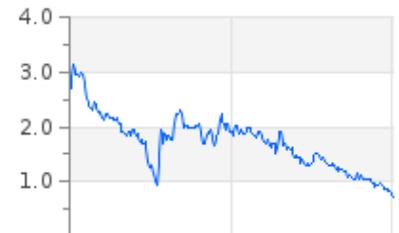
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**Price:** \$0.72

**Market Cap:** \$10.57 m

### 1 Year Share Price Graph



September 2018 March 2019 September 2019

### Share Information

**Code:** QBIO

**Listing:** OTCMKTS

52 week	High	Low
	3.37	0.7099

**Sector:** Medical technology & services

**Website:** [qbiodem.com](http://qbiodem.com)

### Company Synopsis:

*Q BioMed Inc. (OTCQB: QBIO) is a biomedical acceleration and development company. We are focused on licensing and acquiring undervalued and under-appreciated biomedical assets. QBIO is dedicated to providing these target assets, the strategic resources, developmental support, and expansion capital to ensure they meet their potential.*

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