



Biotech Daily

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Daily news on ASX-listed biotechnology companies

Dr Boreham's Crucible: Identifai Genetics

By TIM BOREHAM

ASX code: ID1

Share price: 40 cents

Shares on issue: 191,979,023

Market cap: \$76.8 million

Chief executive officer: Eyal Miller

Board: Yoseph Bornstein (chair), Kobi Caspi, Ata Gokyildirim, Lucy Robb Vujcic

Financials (year to December 31, 2025): revenue nil, net loss \$US1.7 million (\$US1.95 million deficit previously), cash used in operating activities \$US2.2 million (down 17%), cash of \$US669,000 (up 57%) (\$US1.00 = \$A1.43)

Major identifiable holders: Elegant Green Diamonds and Gold LLC 10.63%, M&L Nominees (Black family) 10.01%, Shizim VS Ltd (Messrs Bornstein and Caspi) 9.3%, EHV Israel LP/EHV Advanced 4.84%

On Tuesday, Tel Aviv's genetic screening innovator Identifai Genetics joined the ASX after raising \$10 million in a rare local biotech initial public offer (IPO).

Apart from 'what does Identifai do and why is it different', another question is: 'why is the Israeli company listed on the ASX?'

As it happens there have been plenty of precedents for such a migration across the technology sector generally, with varying degrees of success.

“The ASX is open minded about Israeli innovation, especially in the biotech sector,” says Identifai CEO Eyal Miller. “The feedback we got from our partners in Australia is that the ASX is looking for breakthrough technologies.”

In a recent concession, the ASX also welcomes non-revenue generating listees – so long as they are not far off doing so.

Identifai aspires to satisfy that requirement, with aggressive plans to launch its flagship assay, the artificial intelligence (A.I.) enabled Windrose, in the US within months.

The key to such an expeditious approach is use of the US Food and Drug Administration’s CLIA route (see below).

Mr Miller said the company expected to start commercialization in November.

“We are ready to go and as of the beginning of 2027 we’ll start generating revenue”.

Identifai yourself

Identifai Israel developed Windrose, a non-invasive pre-natal genetic testing platform combining whole-genome sequencing, advanced bio-informatics and artificial intelligence.

Founded in April 2021, Identifai Israel evolved from research carried out a decade ago at Tel Aviv University, by Dr Tom Rabinowitz. Dr Rabinowitz developed the algorithms underpinning the company, within the functional genomics lab of Prof Noam Shomron.

Identifai Israel licenced the technology from the university’s transfer arm, Ramot.

“Since incorporation, the group has advanced from clinical proof-of-concept to an active US-based clinical development program,” Identifai chair Yoseph Bornstein says.

Identifai Genetics was established in August 2025 to acquire Identifai Israel (a company incorporated under Israeli law).

Eyal Miller is a “seasoned” healthcare executive, with nearly three decades of industry experience.

Identifai Israel’s founder and chief scientific officer, Prof Noam Shomron, is an authority in genetics and genomics and was recently elected a Fellow of the US National Academy of Inventors.

A key figure in the Israeli bio-medical industry, Mr Bornstein also co-founded the Nasdaq-listed Microbot Medical. He founded life sciences holding group Shizim VS and has chaired multiple other companies.

Non-executive directors Ata Gokyildirim and Lucy Robb Vujcic are also on the board of the ASX-listed technology minnow Bluglass Limited.

About Windrose

Using a single maternal blood sample from about nine weeks of pregnancy, Windrose can identify a broader range of foetal genetic conditions than conventional non-invasive prenatal testing (NIPT).

The company focuses on monogenic disorders: those caused or controlled by a single gene.

Windrose provides a cell-free DNA (cfDNA) foetal risk assessment for more than 280 “clinically actionable” genes. In other words, clinicians can take action to prevent the disorder.

The company says Windrose aims to address the inability of existing standard NIPT screening products to screen comprehensively for monogenic disorders.

Windrose identifies 296 troublesome genes that are “actionable” during – or shortly after - pregnancy. One example is Pompe disease, caused by a missing enzyme that can be injected during the pregnancy to ameliorate the disorder.

Conditions amenable to intervention during pregnancy include congenital adrenal hyperplasia, foetal anaemia, immune disorders and selected metabolic conditions.

“Time is of the essence,” Mr Miller says. “If those babies are not diagnosed on time ... that has a long-term impact and consequences on foetal morbidity or, in some cases, mortality.”

Current cfDNA screening is primarily recommended for common foetal aneuploidies (a cell with an abnormal number of chromosomes).

But a broader testing of inherited monogenic disease may involve maternal and reproductive-partner testing, or amnio-centesis (extracting a small sample of amniotic fluid from the sac around a foetus).

Currently, mothers routinely undergo a test for Down’s syndrome and to determine whether she is the carrier.

“The father also needs to be screened, but may be out of the picture,” Mr Miller said. “The only way to get clarity on whether the foetus is affected is to undergo an invasive procedure like amnio-centesis.”

One and done

With Windrose, the mother needs only provide one blood sample and her reproductive partner can be elsewhere.

The Windrose test involves taking one sample at the hospital and sending it off to the CLIA -certified lab (see below).

“After that they undergo a genetic sequencing process, which obtains comprehensive information about the entire genome,” Mr Miller says.

The expectant mother or couple discuss risk assessment with a genetic counsellor or obstetrician.

Mr Miller says the earlier the test is carried out the better, in terms of pregnancy management decisions.

“Most of the time the report will be negative so the couple can relax,” Mr Miller says.

Even if the results are positive, there is sufficient time to reassess the risk and do an [invasive] confirmatory test before deciding on a treatment.

Let's be CLIA, it's quicker

CLIA refers to Clinical Laboratory Improvements Amendment, and means that an FDA-certified laboratory can do the test.

“It's much easier, faster, and cheaper,” Mr Miller says.

To ensure quality, only one laboratory nationally manages the assays.

The key is that the company doesn't intend to approach the FDA for clearance.

Identifai's chosen laboratory in San Diego, California is run by Inocras and specializes in genomic testing.

Under the CLIA process a company may not have any contact with the FDA, but they need to be prepared for the agency to ask for validation down the track.

On trial

Via the CLIA route, Indentifai is “good to go” for a US launch, Mr Miller says.

But convincing conservative clinicians to change their practices requires more effort than putting out the ‘open for business’ shingle.

Covering 50 high-risk pregnancies, a validity study in the US and Israel reported “extremely encouraging” 100 percent overall accuracy against the diagnostic reference standard.

The company now plans a 600-patient US clinical validation, at six to eight well-known hospitals in ‘real world’ clinical conditions.

“We will do a head-to-head comparison by taking a saliva sample from the baby once born, which is the ‘ground truth’,” Mr Miller says.

“Or in cases where an invasive procedure has been done, we will use the amniotic test”.

The study should take 12 months.

“You cannot shorten the process because if you're taking the blood sample at nine weeks of gestation, then you need to wait until the baby is born.”

True: bio-science is yet to work out how to ‘cook’ a baby faster.

The company then plans a clinical utility study that appraises the financial benefits of using Windrose (such as reduced hospitalizations).

After that, Identifai hopes to snare a US commercial partner such as a key laboratory.

The US has about 5.5 million pregnancies annually.

Sizing the market

The World Health Organisation estimates that about six percent of babies worldwide are born with a congenital disorder.

Mr Miller notes that of the 140 million deliveries per annum, only about three percent involve serious congenital problems.

Research houses estimate the size of the US NIPT/prenatal genetic testing market at \$US3.9 billion to \$US7.2 billion, growing at a compound annual 10-14 percent per annum.

The company says Windrose can scale from around 10 samples a day at launch, to more than 1,000 samples when fully operational

While the 296 genes screened by Identifai are the most common genetic problems, the company could cover hundreds more by tweaking the algorithm.

“It’s not about the number of genes, but the number that are actionable,” Mr Miller says.

Sizing up the competition

We must stress that Identifai will not be alone in the market.

The NIPT sector is competed by substantive companies including the Nasdaq-listed Natera and Billion To One, as well as Myriad Genetics, Labcorp, Quest Diagnostics, Fulgent Genetics, Roche, Revvity and Illumina.

“The competitive landscape is evolving rapidly,” Identifai says.

The large-scale providers, such as Labcorp and Quest, maintain dominant market share in standard chromosomal NIPT and carrier screening.

“A group of more innovation-driven companies (Natera, Billion To One, Myriad) are actively developing and launching products that extend prenatal genetic screening toward monogenic conditions,” Identifai says. And rather than signalling a saturated market, the presence of large well-capitalized players shows that comprehensive monogenic pre-natal screening is the “next significant frontier in pre-natal genetics”.

Finances and performance

The IPO involved issuing 50 million shares at 20 cents apiece, raising – tada! - \$10 million less costs.

The listing also included just over 10.15 million options, issued to the lead manager, exercisable at six US cents each, between 2033 and 2039.

Post-listing the company had pro-forma cash of just under \$10.7 million – enough to support the trial activity and keep the lights on generally.

Mr Miller estimates a US total addressable market (TAM) of \$US3 billion. If most women do carrier screening – only 800,000 do at the moment – the TAM rises to \$US11-22 billion.

“There’s a lot for us to bite into,” Mr Miller says.

Did someone mention reimbursement?

Most insurers cover basic NIPT screening for up to \$US800. But add carrier (and expanded carrier) screening and the amount jumps to \$US4,400 to \$US4,700 per test.

“We can leverage on the current coding.”

For insurers the cost of not doing the testing can be enormous, given the suffering and difficulties an untreated baby could go on to suffer through their lifetime.

After listing, Identifai shares traded between 21.5 cents and 54 cents.

Dr Boreham’s diagnosis:

Given the extent of existing competition, Mr Miller says clinicians and facilities often ask why they should deal with a small Israeli company.

The proposed validation test should provide the requisite comfort.

Given the similar US reimbursement for Windrose to other tests, the clinicians and hospitals won't be disadvantaged financially.

The company plans to focus on the US market initially - and sensibly - other markets with low, CLIA-like regulatory hurdles could follow.

This includes Europe where birth rates are plummeting, but folk haven't quite given up on reproduction.

Mr Miller says that in providing the first and the only genome-wide approach platform, Identifai addresses an unmet market need with "true innovation".

While revenue expectations are unclear, Mr Miller's message to investors is "prepare to be amazed".

He says: "We are going to create a lot of buzz in the US and once a commercial partner joins in that will create even more traction."

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. Hopefully this is not a source of complete amazement to readers