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AnPac Bio-Medical Science Co., Ltd. (ANPC - NASDAQ)

Class III Registration Testing Approved

Target price is based on a 20x multiple of 2027 EPS. The result is discounted to present at a 25% rate. Revenues represent contributions from physical checkup packages and cancer screening tests in China and the United States.

Current Price (2/11/2021)	$5.90
Valuation	**$8.00**

OUTLOOK

AnPac Bio is developing advanced cancer screening with its CDA technology that is able to detect the likelihood of 26 different cancers. The screening tool can serve as a valuable role in early detection and prevention of this common disease.

Revenues are solely generated in China from cancer screening and detection and physical checkup packages. Future growth will come from access to the Chinese hospital market and launch of testing services in the United States.

AnPac is focused on obtaining the license and authorization to provide services more broadly in China. The company is also working to launch testing services in the US having obtained a CLIA & CAP approved lab in California. Efforts to conduct clinical trials to validate the diagnostic platform and to seek FDA approval of its CDA testing platform is also underway.

Commercialization plans include obtaining certification to provide CDA testing services in hospitals in China and completing screening studies performed in the US. ANPC will initially sell the diagnostic as an LDT and later seek FDA approval for its tests, allowing for broader use.

SUMMARY DATA

52-Week High	**12.00**
52-Week Low	**3.15**
One-Year Return (%)	**-38.9**
Beta	**N/A**
Average Daily Volume (sh)	**1,304,285**
Shares Outstanding (mil)	**11.2**
Market Capitalization ($mil)	**66.1**
Short Interest Ratio (days)	**0.01**
Institutional Ownership (%)	**0.63**
Insider Ownership (%)	**37.8**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2020 Estimate	**N/A**
P/E using 2021 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**Above Average**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(In millions of US$)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2019	$0.0 A	$0.0 A	$0.0 A	$1.6 A	$1.6 A
2020	$0.0 A	$0.6 A	$1.2 E	$1.3 E	$3.1 E
2021					$6.5 E
2022					$11.5 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2019	$0.00 A	$0.00 A	$0.00 A	-$1.62 A	-$1.62 A
2020	$0.00 A	-$0.72 A	-$0.16 E	-$0.11 E	-$0.99 E
2021					-$0.44 E
2022					-$0.23 E

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WHAT'S NEW

Class III Registration Advancing in Lung Cancer

Since our previous report, AnPac Bio-Medical Science Co., Ltd. (NASDAQ: ANPC) has announced that its Cancer Differentiation Analysis (CDA) technology demonstrated further progress in the ability to detect pre-cancer diseases, it was granted a US patent for multi-cancer detection and that the China National Medical Products Administration (NMPA) approved the start of registrational testing in support of AnPac's Class III medical device approval.

Progress in Detecting Pre-cancer Diseases

On December 14, 2020, AnPac declared significant progress in detecting pre-cancer diseases. Using a variety of its proprietary sensor technologies, AnPac evaluated over 13,000 individuals in a follow up study. The results demonstrated CDA's ability to classify patients into varying levels of cancer risk for more than 20 types of pre-cancer diseases, subsequently confirmed by hospital or physical check-ups. CDA was particularly adept at detecting thyroid nodule/tumor and pulmonary nodule with over 90% confirmed pre-cancer patients that had received a medium to high-risk CDA designation. Out of the roughly 13,000 subjects, CDA screened out pre-cancer cases at ~4.5x that of cancer cases, demonstrating CDA's potential in cancer prevention. The study and results are in the process of formal publication.

AnPac's CDA technology leverages the biophysics of blood for screening. The company leverages a number of detection technologies to achieve this end, including novel sensor design, sensor fabrication, detection process, signal collection, signal processing and proprietary algorithms. Identifying pre-cancer diseases serves a valuable role as an early warning for cancer, calling for intervention when it matters most.

Early detection has a dramatic impact on survival. For example, the five-year survival rate for lung cancer is well over 50% for cases when the disease is localized in the lungs but only 5% in more advanced stages.[1] There are a broad variety of treatments for cancer; however, they become less effective when the disease has progressed to advanced stages. Early detection and diagnosis are crucial for efficiently and effectively treating this common malignancy. There are many screening tools available; however, they suffer from low levels of accuracy, high costs, inconvenience and discomfort and a need for multiple tests to cover the most common cancer types. Results from evaluating CDA in pre-cancer diseases hold promise as a scalable, and comprehensive screen for early intervention.

AnPac's announcement marked the completion of a prospective larger population screening, using CDA, of over 110,000 individuals and over 150,000 samples. The follow-up tracked the course of patients of varying cancer risk as assessed by CDA.

US Patent Granted

AnPac received approval for patent number 10,895,573, announced February 1, 2021. The patent is entitled "Apparatus for Detecting Tumor Cells" and was granted on January 19, 2021 and describes an apparatus for interacting with a biological subject to detect circulating tumor cells. It is able to send a signal to the biological sample and receive a response to the signal from the biological entity. The patent has 38 claims, covering a range of novel features for multi-cancer detection, including the detection apparatus, components, reagents, mechanisms and detection parameters, including biophysical properties.

NMPA Approval for Commencement of Registration Testing

We previously reported that AnPac had applied for a Class III medical device in 2019. The firm has now been approved to begin testing the CDA device. In an update on February 8, 2021, AnPac disclosed that registration testing for its Class III medical device certification was approved by the NMPA to begin, marking a milestone for commercialization in China. The application specifies a lung cancer auxiliary diagnosis medical device and was a strategic decision. While CDA can detect risk across a wide variety of cancers, regulatory approval will initially target just one of China's most prevalent cancers.[2] The narrow focus in lung was pursued in order to expedite the regula-

[1] American Cancer Society, Lung Cancer Survival Rates
[2] Lung Cancer Most Common Cancer In China: Air Pollution Taking Its Toll With Estimates Of 7,500 Deaths Per Day (medicaldaily.com)

tory process. CDA requires additional testing to determine the specific cancer; therefore, an auxiliary test, available via third party, is expected to accompany CDA to obtain approval in lung cancer.

Successfully achieving the objectives of the test will allow AnPac to place CDA diagnostic equipment in hospitals, the primary source of annual physical checkups for 100 million Chinese citizens every year. We estimated that AnPac might obtain this authorization by late 2021, but progress will depend on clinical bandwidth, which may be limited by the pandemic and associated containment measures. The process for NMPA approval typically takes three years and was begun in December 2018.

The process for filing for NMPA approval began in December 2018 when AnPac applied for medical device registration. Since then, the device was classified by the NMPA as a Class III device (highly regulated). AnPac has optimized and tested the device internally and has employed third party testing and validation. AnPac has obtained the necessary certification for the device testing laboratory where the recently NMPA-approved testing will begin. Pending successful product registration testing, the next step will be a clinical trial. AnPac anticipates that the clinical trial will be conducted in at least two qualified medical institutions, targeting enrollment of 300 subjects for each clinical site. The trial will differ from conventional clinical trials as the results will primarily only require sample collection and confirmation of the cancer using a gold-standard technique. There is no treatment involved which is favorable in terms of time and cost. Timelines will become clearer once the trial is underway, and uncertainties regarding clinical availability and throughput will be clarified. Pending favorable results from the trial, AnPac leadership expects CDA to receive the benefit of an accelerated pathway under the NMPA, but cautions that COVID-19 related therapies and products have taken priority.

Key reasons to own AnPac Bio shares:

- **Swiftly growing demand for cancer screening**
- **Rapid, inexpensive screening process for the most common cancers using a single blood sample**
- **High incidence and prevalence of cancer in primary markets of China and US**
- **Effective screening approach using biophysical properties**
    - **Substantial literature supportive of the approach**
    - **Prospective studies presented at ASCO demonstrate high accuracy**
- **Physical labs in place in China and the US**
- **Extensive history of research associating biophysical properties of blood with cancer**
- **Opportunity to expand suite of products to provide additional services**
    - **Therapy selection**
    - **Treatment monitoring**
    - **Genomic testing**
- **Development platform that can be applied to many genetic tests and cellular therapy applications**

Summary

AnPac is approaching diagnostic cancer screening from a new direction that identifies the biophysical properties of blood to identify cancer risk. Not only is this approach uncorrelated and potentially synergistic with other testing approaches that use DNA sequencing but it is also much less costly with simpler detection mechanisms. The company is in an attractive market as there are an estimated 18 million cases of cancer a year, and as the likelihood of the disease increases with age, there is also a demographic tailwind to anticipated demand as the older population is expected to increase at a faster rate than the population overall. Research has shown that catching cancer early can have a dramatic impact on survival and on the total cost of treatment, which can make a strong economic case to employers and health plans who want to keep their people on the job and reduce spending on preventable disease. Current screening approaches are poor and present accuracy levels that create an undue burden on the health care system and on the patients who use them, either through unnecessary worry, cost and procedures for a false positive, or failure to catch the disease for a false negative.

In the past several months since our last update, AnPac publicized results showing CDA's ability to screen for pre-cancer disease. AnPac also was granted a US patent for multi-cancer detection. Additionally, the company received approval from the NMPA to begin registration testing, targeting commercialization in China. We maintain our price target of $8.00 per share.

PROJECTED FINANCIALS

AnPac Bio-Medical Science Co., Ltd. - Income Statement

AnPac Biomedical Science Co.	2019 A	1H A	Q3 E	Q4 E	2020 E	2021 E	2022 E
Total Revenues ($USD)	**$1,558**	**$573**	**$1,200**	**$1,300**	**$3,073**	**$6,527**	**$11,489**
Revenue Growth	2.6%	3.3%	106.7%	207.3%	97.2%	112.4%	76.0%
Cost of Goods Sold	$869	$313	$600	$650	$1,563	$2,891	$4,825
Gross Margin	44.2%	45.4%	50.0%	50.0%	49.1%	55.7%	58.0%
Gross Profit	**$689**	**$260**	**$600**	**$650**	**$1,510**	**$3,636**	**$6,663**
Selling & Marketing	$1,958	$661	$522	$525	$1,708	$2,240	$2,417
Research & Development	$1,413	$1,052	$320	$350	$1,722	$1,400	$1,540
General & Administrative	$10,167	$7,175	$1,500	$1,300	$9,975	$6,460	$6,718
Other Income	($54)	($7)	$0	$0	($7)	$0	$0
Operating Income	($12,795)	($8,621)	($1,742)	($1,525)	($11,888)	($6,464)	($4,012)
Operating Margin	-821.2%	*-1504.5%*	*-145.2%*	*-117.3%*	*-386.9%*	*-99.0%*	*-34.9%*
Interest Income (Expense)	($375)	($73)	($90)	($90)	($253)	($360)	($360)
Total Other Income	($1,457)	$753	$0	$0	$753	$0	$0
Pre-Tax Income	($14,546)	($7,938)	($1,821)	($1,605)	($11,364)	($6,783)	($4,347)
Income Tax	$31	$5	$5	$5	$15	$20	$13
Tax Rate	0%	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($14,515)	($7,933)	($1,816)	($1,601)	($11,349)	($6,763)	($4,334)
Reported EPS	**($1.62)**	**($0.72)**	**($0.16)**	**($0.11)**	**($0.99)**	**($0.44)**	**($0.23)**
YOY Growth	122.2%				*-39.2%*	*-55.2%*	*-48.4%*
Shares Outstanding	8,938	10,952	11,500	14,000	11,500	15,300	19,000

Source: Company Filing // Zacks Investment Research, Inc. Estimates

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HISTORICAL STOCK PRICE

AnPac Bio-Medical Science Co., Ltd. – Share Price Chart[3]



[3] Source: Zacks Research System

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