Zacks Small-Cap Research

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AnPac Bio-Medical Science Co., Ltd.

(ANPC - NASDAQ)

Opening The Door To Treatment

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 (5/28/2021)	$4.32
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 a valuable role in early detection and prevention of this common disease.

Historical 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 that come from approval of Class III registration. 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. 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	**12.09**
52-Week Low	**3.15**
One-Year Return (%)	**-43.2**
Beta	**1.86**
Average Daily Volume (sh)	**1,115,156**
Shares Outstanding (mil)	**12.7**
Market Capitalization ($mil)	**54.9**
Short Interest Ratio (days)	**0.03**
Institutional Ownership (%)	**3.64**
Insider Ownership (%)	**32.2**
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-Instruments**

ZACKS ESTIMATES

Revenue

(In millions of US$)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2020	$0.1 A	$0.4 A	$0.0 A	$2.6 A	$3.1 A
2021	$0.3 A	$1.5 E	$1.6 E	$1.9 E	$5.4 E
2022					$8.9 E
2023					$12.0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2020	-$0.28 A	-$0.44 A	$0.00 A	-$0.39 A	-$1.10 A
2021	-$0.37 A	-$0.13 E	-$0.11 E	-$0.10 E	-$0.67 E
2022					-$0.38 E
2023					-$0.25 E

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WHAT'S NEW

First Quarter 2021 Operational and Financial Results

On May 27, 2021, AnPac Bio-Medical Science Co., Ltd. (NASDAQ: ANPC) issued a press release summarizing its financial and operational results for the first quarter 2021, ending March 31. A major highlight of the first quarter was the approved start of registration testing for CDA technology as a Class III medical device. Following the end of the quarter, AnPac's board approved the formation of a joint venture to pursue cancer treatment, marking an expansion from AnPac's detection repertoire into the treatment space.

Highlights for the quarter include:

- Achieving a first quarter record number of CDA tests;
- Patent entitled "Apparatus for Detecting Tumor Cells" granted;
- Development and testing for new generation CDA Pro Sensor;
- NMPA approval to begin registration testing;
- Ongoing follow-up of CDA-tested individuals' health outcomes;
- Continued development of cancer risk assessment database;

For the first quarter 2021, compared to the first quarter 2020:[1,2]

- Revenues were $333,000 vs $132,000, an increase of 152% driven by higher average selling price attributable to the sale of more comprehensive tests. All revenues were generated from CDA testing.
- Cost of revenues was $139,000, up 56% from $89,000;
- Gross margin improved sharply to 58.4% from 32.7% on higher selling prices for CDA tests, improved operational efficiency and higher volumes of CDA tests;
- Selling and marketing expenses totaled $590,000, up 15% from $515,000;
- Research and development expenses totaled $512,000, rising 22% from $421,000;
- G&A expenses were $2,934,000 versus $2,807,000, up 5%;
- Total loss available to ordinary shareholders was ($4.43) million vs ($3.02) million, or ($0.37) and ($0.28), respectively.

As of March 31, 2021, cash and equivalents stood at $1.4 million.

Joint Venture Launch

AnPac's Board of Directors approved a joint venture between the company and its founder and chairman, Dr. Chris Chang Yu, along with other individuals to develop a new cancer treatment technology and related products. The May 25 announcement stated that the effort will be based on AnPac's early-stage cancer detection work, correlations between changes in biophysical properties in the tumor micro-environment and cancer occurrence observed by multiple research groups including AnPac Bio. The approach plans to use key treatment modules fabricated by integrated circuit technology in conjunction with certain reagents, to target biophysical properties exhibiting abnormal ranges within pre-cancer and cancer populations. Testing of the technology is expected to begin in 3Q:21 followed by an application for a Class III medical device application to the Chinese National Medical Products Administration (NMPA) in 3Q:22.

[1] Note that our percentage change is based on reported income statement values in US Dollars which differs from AnPac's calculation using Renminbi.
[2] USD values converted from AnPac reported RMB values using the average daily conversion rate for the quarter.

Class III Registration Advancing in Lung Cancer

AnPac applied for a Class III medical device registration certificate in December 2018 to use the CDA device for multi-cancer diagnosis. In an update on February 8, 2021, AnPac disclosed that registration testing for its Class III medical device certification was approved to begin by the NMPA, marking a milestone on the road to further commercialization in China. The application falls into the category of a lung cancer auxiliary diagnosis medical device.

Pursuing a single site for cancer screening rather than a pan-cancer approach was a strategic decision that is expected to save time given its improved tractability. 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. Further applications in pan-cancer indications are expected and the company will pursue the routes that most expediently clear the device to generate testing revenues.

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 estimate 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 when AnPac applied for medical device registration. Since then, the device was classified by the NMPA as a highly regulated Class III device. AnPac has optimized and tested the device internally and 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 in the approval process which is favorable in terms of time and cost. Timelines will be brought into relief once the trial is underway and uncertainties regarding clinical availability and throughput are 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 efforts have taken priority.

In the most recent conference call, management provided further detail regarding the steps required for obtaining Class III Registration, summarized below.

- Deliver the CDA machine to the lab for testing
- Conduct and pass required testing
- Develop clinical study design
- Begin clinical portion of testing with three machines delivered to three hospitals
    - Three to six month timeline to conduct necessary studies
- Collect, analyze and submit data package to the Chinese regulatory authorities for review
- Address additional requests for data
- Receive approval when all requirements satisfied and questions answered

The process for obtaining approval can vary and depends heavily on what the regulatory authorities want to see from the submission. The timeline could extend from eight months to a year and we expect further updates as the steps in the process are clarified.

Detecting Pre-cancer Diseases

For all of the individuals who have taken the commercial CDA tests, AnPac follows up with them at regular intervals to assess the accuracy of the tests. The study began in 2017 and has a target duration of five years. On December 14, 2020, AnPac declared significant progress in detecting pre-cancer diseases with this work and had evaluated over 13,000 individuals in the study. The results demonstrated CDA technology'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 group of subjects, CDA screened out pre-cancer cases at a rate 4.5x that of cancer cases, demonstrating CDA's potential in early cancer intervention. The study and results are in the process of formal publication.

In an update from the previous study communication, a March 2021 interim readout on the study was provided. Up to the cutoff date, AnPac had contacted 23,857 individuals who had received the screening test. Of this group, 14,127 of the test recipients provided substantive feedback on their health condition and disease development. 1,928 of the respondents had been diagnosed with major diseases by third-party hospitals or medical institutions within two years of taking the CDA test. 209 of the individuals were diagnosed with cancers, 962 with pre-cancers or benign tumors and 757 with major non-cancerous diseases. All of these diagnoses were in the high and medium cancer risk test result groups.

Exhibit I – Interim Study Results

Cancer Risk Test Result	Feedback	Disease Diagnosis	Proportion
High	836	209	25.0%
Medium	11,328	1,719	15.2%
Low	1,963	0	0%
Total Respondents	14,127	1,928	

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 over 50% for cases when the disease is localized in the lungs but only 5% in more advanced stages.[3] There is a broad selection of treatments for cancer; however, the options are 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 US 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 which 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 it. 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.

New Sensor

AnPac announced in March that they had developed a second generation sensor for cancer detection that exhibits improved signal and yield performance. The new iteration is called the CDA Pro Sensor (CDAPS) and it offers improved detection signal stability, sensor device yield, cost and detection accuracy. Advancements made in design, fabrication and packaging processes are expected to enhance the competitiveness of AnPac's cancer screening.

AnPac is now in the process of transitioning to the new sensor in its CDA machines, first in China then in the United States. Tests using the new sensor began earlier this year in the Philadelphia lab and will be used in the devices seeking FDA approval.

[3] American Cancer Society, Lung Cancer Survival Rates

Company Milestones

- IPO on NASDAQ – January 2020
- Addition of new insurance customers – February 2020
- San Jose lab CAP Accreditation – March 2020
- Philadelphia lab opening – July 2020
- Philadelphia lab CLIA Lab Certification – August 2020
- New contract with Beijing Yuan Jian Health Management – June 2020
- Filing of various patent applications in the US - 2020
- Regain compliance with NASDAQ listing requirement – March 2021
- 237 patent applications and 142 patents granted to date – March 2021
- Dr. Yu & AnPac Joint Venture – May 2021
- Class III Medical Device Registration Certificate –2021 / 2022

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 per 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.

AnPac has recently publicized results showing CDA's ability to screen for pre-cancer disease. AnPac also was granted a US patent for multi-cancer detection and has upgraded the sensor used to produce CDA values. The company has begun registration testing for the NMPA, targeting commercialization in China and launched a joint venture to develop new cancer treatment technology. Activity has accelerated in the first quarter of 2021 with revenue growth of ~150% over prior year levels. We maintain our price target of $8.00 per share.

PROJECTED FINANCIALS

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

AnPac Biomedical Science Co.	2020 A	Q1 E	Q2 E	Q3 E	Q4 E	2021 E	2022 E	2023 E
Total Revenues ($USD)	**$3,143**	**$333**	**$1,518**	**$1,643**	**$1,910**	**$5,404**	**$8,931**	**$12,024**
Growth	101.7%	152.3%				71.9%	65.3%	34.6%
Cost of Goods Sold	$1,169	$139	$683	$723	$802	$2,347	$3,751	$4,689
Gross Margin	62.8%	58.4%	55.0%	56.0%	58.0%	56.6%	58.0%	61.0%
Gross Profit	**$1,974**	**$194**	**$835**	**$920**	**$1,108**	**$3,057**	**$5,180**	**$7,335**
Selling & Marketing	$3,015	$590	$550	$570	$590	$2,300	$2,417	$2,750
Research & Development	$1,774	$512	$350	$350	$350	$1,562	$1,540	$1,500
General & Administrative	$11,457	$2,934	$1,615	$1,615	$1,615	$7,779	$8,090	$8,414
Other Income	$219	$0	$0	$0	$0	$0	$0	$0
Operating Income	($14,491)	($3,842)	($1,680)	($1,615)	($1,447)	($8,584)	($6,867)	($5,329)
Operating Margin	*-461.1%*	*-1153.6%*	*-110.7%*	*-98.3%*	*-75.8%*	*-158.8%*	*-76.9%*	*-44.3%*
Interest Income (Expense)	($175)	($95)	($90)	($90)	($90)	($365)	($360)	($360)
Total Other Income	$2,306	($531)	$0	$0	$0	($531)	$0	$0
Pre-Tax Income	($12,346)	($4,435)	($1,760)	($1,695)	($1,528)	($9,417)	($7,184)	($5,656)
Income Tax	$13	$3	$5	$5	$5	$18	$22	$17
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($12,333)	($4,432)	($1,754)	($1,690)	($1,523)	($9,399)	($7,163)	($5,639)
Reported EPS	**($1.10)**	**($0.37)**	**($0.13)**	**($0.11)**	**($0.10)**	**($0.67)**	**($0.38)**	**($0.25)**
Shares Outstanding	11,190	11,958	13,500	15,400	15,600	14,115	19,000	23,000

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

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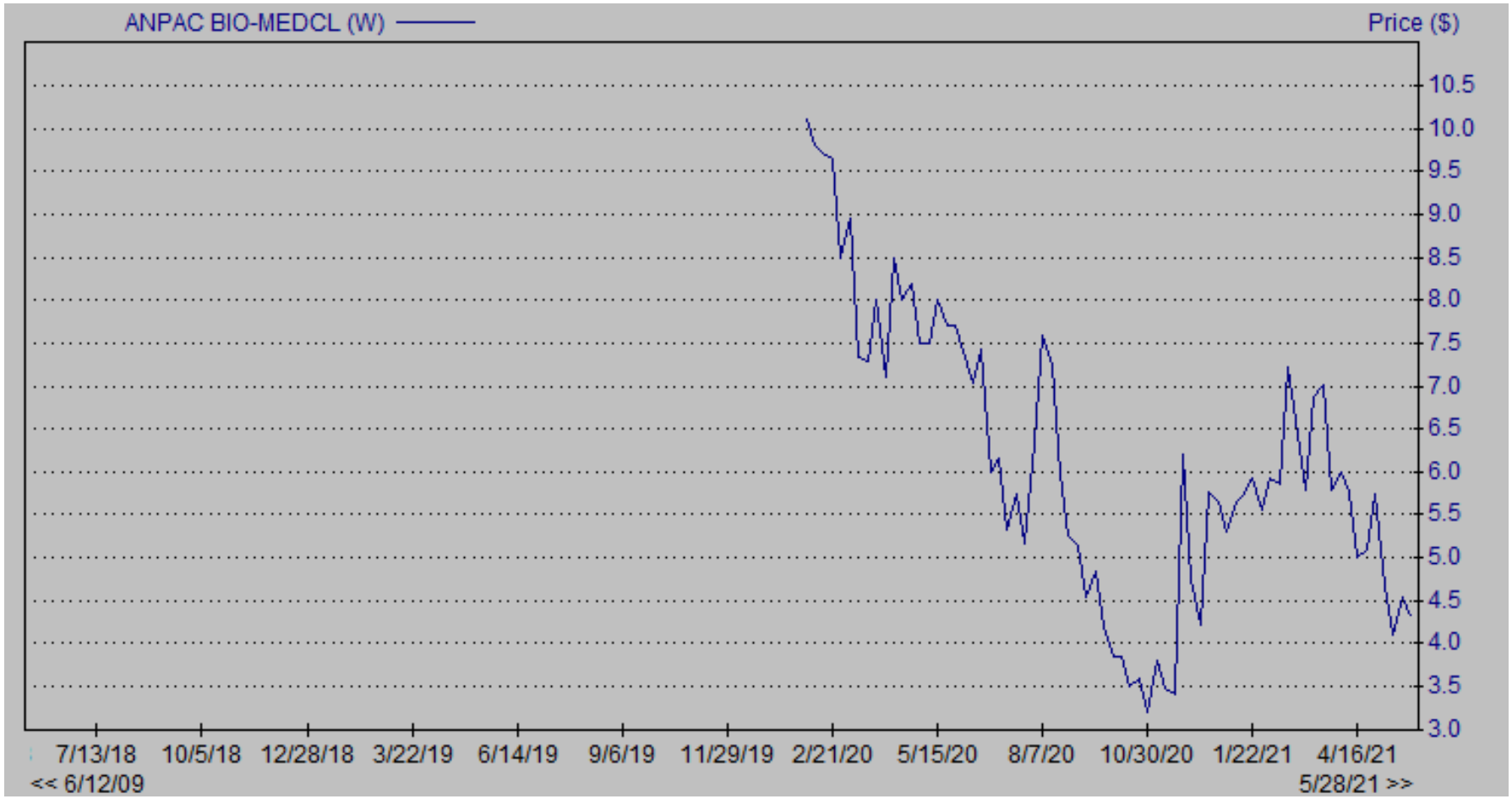
HISTORICAL STOCK PRICE

AnPac Bio-Medical Science Co., Ltd. – Share Price Chart[4]



[4] Source: Zacks Research System

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